NKR 4 PICO 7 Topical steroids in the prophylaxis of pseudophakic cystoidmacular edema

Review information

Authors

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Citation example: S, [Empty name]. NKR 4 PICO 7 Topical steroids in the prophylaxis of pseudophakic cystoidmacular edema. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Asano 2008

Methods	Multicenter RCT Compares PCME evaluated by fluorescein angiography in patients randomized to diclofenac or betamethasone
Participants	Patients with age-related cataract undergoing phacoemulsification
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	The test drugs were assigned to patients at random after the controller validated that the assigned therapy was indistinguishable from the alternative therapy. The controller kept the assignment code until completion of the study. The controller created an emergency code, which was given to the principal investigator in an envelope
Blinding of participants and personnel (performance bias)	Low risk	Blinded
Blinding of outcome assessment (detection bias)	Low risk	Blinded
Incomplete outcome data (attrition bias)	Low risk	Low drop out Obs High risk for visual acuity
Selective reporting (reporting bias)	Low risk	All that was stated to be measured was measure
Other bias	Low risk	None detected

Choi 2016

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention: Topikal (øjendråbe) behandling med steroid-præparat ● *Mean age (sd)*: ● *No. of males (%)*: Control: Topikal behandling med NSAID-præparat ● *Mean age (sd)*: ● *No. of males (%)*: Overall ● *Mean age (sd)*: ● *No. of males (%)*: **Included criteria:** Inclusion criteria included patients who had phacoemulsification cataract surgery and intraocular lens (IOL) implantation performed by the same surgeon (HKL) without intraoperative complications. **Excluded criteria:** Patients with diabetic mellitus, a history of ocular infection or inflammation, trauma or surgery, corneal opacities, or abnormal corneal astigmatism patterns were excluded. Patients initially included in the study were later discontinued if they had intraoperative complications or postoperative complications. **Pretreatment:** None significant.
Interventions	**Intervention Characteristics** Intervention: Topikal (øjendråbe) behandling med steroid-præparat ● *Description*: Prednisolone acetate 1.0% predforte ● *Duration of intervention*: 3 weeks ● *Dose*: Dråber givet hver 2. time på op dagen, 2 dråber hver 4 time første uge, 2-4 dråber dgl i 3 uger ● *Follow-up time after EoT*: 20 weeks Control: Topikal behandling med NSAID-præparat

	● *Description*: Bromfenac 0.1% ● *Duration of intervention*: 3 weeks ● *Dose*: Dråber givet hver 2. time på op dagen, 2 dråber hver 4 time første uge, 2-4 dråber dgl i 3 uger ● *Follow-up time after EoT*: 20 weeks
Outcomes	*Cystoidt makulaødem* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Slutvisus (Visus postop)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: Logmar ● **Direction**: Lower is better ● **Data value**: Endpoint *Risikomål: Intraokulær trykstigning* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Samlet antal adverse events (som defineret af studie)* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: No information of how the allocation sequence was generated
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: No information of how the allocation sequence was concealed
Blinding of participants and personnel (performance bias)	Unclear risk	Judgement Comment: No information
Blinding of outcome assessment (detection bias)	Low risk	Judgement Comment: All outcome assessors were blinded
Incomplete outcome data (attrition bias)	Unclear risk	Judgement Comment: Ingen information der kan afgøre om frafald var ens i de to grupper
Selective reporting (reporting bias)	Low risk	Judgement Comment: Ingen protokol tilgængelig, men alle forventelige outcomes er rapporteret i forhold til studiets fokus
Other bias	Low risk	Judgement Comment: Appears to be free from other sources of bias

Demco 1997

Methods	RCT, 2 weeks treatment prednisolone acetat 1% vs diclofenac sodium 0.1%
Participants	
Interventions	
Outcomes	
Notes	Supported by a grant from CIBA Vision

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	"randomly assigned in a masked fashion"
Blinding of participants and personnel (performance bias)	Low risk	blinded
Blinding of outcome assessment (detection bias)	Low risk	blinded
Incomplete outcome data (attrition bias)	Low risk	Drop outs: 7 in diclo, 8 in predni
Selective reporting (reporting bias)	Low risk	Only CME missing
Other bias	Low risk	None detected

El-Harazi 1998

Methods	RCT Compares the efficacy of ketorolac tromethamine 0.5%, diclofenac sodium 0.1%, and prednisolone acetate 1% in reducing flare and cells following cataract surgery. Outcome measures: inflammation and IOP Follow-up 1, 7, and 28 days postoperatively
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Identical bottles
Blinding of participants and personnel (performance bias)	Low risk	Blinded
Blinding of outcome assessment (detection bias)	Low risk	Blinded
Incomplete outcome data (attrition bias)	Low risk	Only 2 drop outs
Selective reporting (reporting bias)	Low risk	Visual acuity and macular oedema missing
Other bias	Low risk	None detected

El-Harazi 1998 B

Methods	
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Identical bottles
Blinding of participants and personnel (performance bias)	Low risk	Blinded
Blinding of outcome assessment (detection bias)	Low risk	Blinded
Incomplete outcome data (attrition bias)	Low risk	Only 2 drop outs
Selective reporting (reporting bias)	Low risk	Visual acuity and macular oedema missing
Other bias	Low risk	None detected

Endo 2010

Methods	RCT comparing foveal and perifoveal thickness by OCT in patients randomized to bromfenac or steroid
Participants	Patients with age-related cataract undergoing phacoemulsification
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	High risk	Open label
Blinding of outcome assessment (detection bias)	Unclear risk	Open label
Incomplete outcome data (attrition bias)	High risk	High drop out
Selective reporting (reporting bias)	Unclear risk	Unclear reporting

Other bias	Low risk	None detected

Hirneiss 2005

Methods	RCT Compares prednisolone 1% to rimexolone 1% or ketorolac tromethamine 0.5% Outcome measures: visual acuity, IOP, slitlamp, flare Follow-up 1, 3, 5, 14 and 2 days postoperative
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	Low risk	Blinded veils, self-administration
Blinding of outcome assessment (detection bias)	Low risk	Blinded veils
Incomplete outcome data (attrition bias)	Low risk	5 drop outs, fairly evenly distributed between groups
Selective reporting (reporting bias)	Low risk	No obvious outcomes missing
Other bias	Low risk	None detected

Hirneiss 2005 B

Methods	
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	Low risk	Blinded veils, self-administration
Blinding of outcome assessment (detection bias)	Low risk	Blinded veils
Incomplete outcome data (attrition bias)	Low risk	5 drop outs, fairly evenly distributed between groups
Selective reporting (reporting bias)	Low risk	No obvious outcomes missing
Other bias	Low risk	None detected

Holzer 2002

Methods	RCT Compares ketorolac tromethamine 0.5% to loteprednol etabonate 0.5% Outcome measures: inflammation (slitlamp), flare and KOWA cell and IOP Follow-up 1, 4, 7, and 30 days postoperatively
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Identical bottles
Blinding of participants and personnel (performance bias)	Low risk	Blinded
Blinding of outcome assessment (detection bias)	Low risk	Blinded

Incomplete outcome data (attrition bias)	Low risk	1 excluded due to preexistiing condition
Selective reporting (reporting bias)	Low risk	No obvious outcomes missing
Other bias	Low risk	None detected

Laurell 2002

Methods	RCT Compares dexamethasone, diclofenac and placebo Outcome measures: inflammation Follow-up. 1, 3, 8 days, 2 and 4 weeks, 2 and 6 months and 1, 2, and 4 years postoperatively
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The patients were randomly allocated to three equal sized groups (n=60). Randomisation was done by a computer in blocks of six patients (randomly permuted blocks, SAS/PLAN procedure).
Allocation concealment (selection bias)	Low risk	All bottles were white and non-transparent. They were delivered from the pharmacy with identical labels except for the randomisation number. There was a coding envelope for each number.
Blinding of participants and personnel (performance bias)	Low risk	Blinded
Blinding of outcome assessment (detection bias)	Low risk	Blinded
Incomplete outcome data (attrition bias)	Low risk	Low drop out rates
Selective reporting (reporting bias)	Low risk	No reporting on cells or PCMO
Other bias	Low risk	None detected

Missotten 2001

Methods	RCT Compares the efficacy and safety of topical 0.1% indomethacin with 0.1% dexamethasone after cataract surgery. Outcome measures: inflammation Follow-up: 1, 3, 10 and 30 days postoperatively
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomly assigned to one of the two treatment groups according to a randomisation list produced using the PROC RANUNI procedure (SAS Institute). A balanced block size of 4 was used.
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	Low risk	Described as 'double blind'
Blinding of outcome assessment (detection bias)	Low risk	Described as 'double blind'
Incomplete outcome data (attrition bias)	Low risk	129 out 145 completed, ITT
Selective reporting (reporting bias)	Low risk	Only PCMO missing
Other bias	Low risk	None detected

Miyake 2000

Methods	RCT? (or maybe just interventional). RCT according to email from author Compares the effect of dicolefac to fluorometholone Outcome measures: inflammation and cystoid macular edema Follow-up: 3 days and 1,2, 5 and 8 weeks postoperatively
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Email from author: "The envelop method means the medication(s) are indicated inside the envelop."
Blinding of participants and personnel (performance bias)	Low risk	Email from author "All three studies were done in a blind fashion where the patients and the assessors dont know the medications"
Blinding of outcome assessment (detection bias)	Low risk	Email from author "All three studies were done in a blind fashion where the patients and the assessors dont know the medications"
Incomplete outcome data (attrition bias)	High risk	high drop out
Selective reporting (reporting bias)	Low risk	All outcomes included
Other bias	Low risk	None detected

Miyake 2007

Methods	RCT comparing the incidence of PCME at 2 and 4 weeks postoperatively in patients randomized to diclofenac or fluorometholone
Participants	Patients with age-related cataract undergoing phacoemulsification
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Each patient was randomly assigned to one of the two groups by one of the authors (SA), using the envelope method,
Blinding of participants and personnel (performance bias)	Low risk	Mail from author: patients and assessor were blinded
Blinding of outcome assessment (detection bias)	Low risk	Mail from author: patients and assessor were blinded
Incomplete outcome data (attrition bias)	Low risk	total of 6 drop out not related to treatment
Selective reporting (reporting bias)	Low risk	only cell not rep
Other bias	Low risk	none detected

Miyake 2011

Methods	RCT comparing the angiographic incidence of PCME at 5 weeks postoperatively in patients randomized to nepafenac or fluorometholone
Participants	Patients with cataract undergoing phacoemulsification
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	Identical containers
Blinding of participants and personnel (performance bias)	Low risk	Identical containers
Blinding of outcome assessment (detection bias)	Low risk	CME evaluated in doubel blinded manner and mail saying: all blinded

Incomplete outcome data (attrition bias)	Low risk	All included in safety evaluation, one excluded from flouro group as he wanted bilat procedure, 1 because of humeral fracture, 1 because of posterior lens capsule rupture during surgery, 2 from nepa group excluded from post CME evaluation, one due to macualr degeneration and one declined procedure
Selective reporting (reporting bias)	High risk	IOP measured but not reported
Other bias	Low risk	None detected

Miyanaga 2009

Methods	RCT Compares bromfenac versus betamethasone or bromfenac + betamethasone Outcome measures: inflammation and PCME Follow-up: 1 and 3 days, 1 and 2 weeks and 1 and 2 months
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias)	Unclear risk	Not described
Incomplete outcome data (attrition bias)	Low risk	1 drop out
Selective reporting (reporting bias)	Low risk	No obvious outcomes missing
Other bias	Low risk	None detected

Reddy 2000

Methods	RCT Compares diclofenac sodium 0.1% to dexamethasone phosphate 1% Outcome measures: inflammation, IOP Follow-up: 1,3 , 7, 14 and 21 days postoperatively
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated
Allocation concealment (selection bias)	Low risk	Identically sealed bottles
Blinding of participants and personnel (performance bias)	Low risk	Patients, nursing staff and surgeons were masked to topical medications
Blinding of outcome assessment (detection bias)	Low risk	Patients, nursing staff and surgeons were masked to topical medications
Incomplete outcome data (attrition bias)	Low risk	5 drop outs from each group, 10 total
Selective reporting (reporting bias)	Low risk	Bad reporting but none missing
Other bias	Low risk	None detected

Roberts 1995

Methods	RCT Compares diclofenac sodium with prednisolone acetate for the control of postoperative inflammation after cataract surgery. Outcome measures: inflammation Follow-up: 1 day, 1 week and 1 month
Participants	
Interventions	
Outcomes	

Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	Low risk	Blinded
Blinding of outcome assessment (detection bias)	Low risk	Blinded
Incomplete outcome data (attrition bias)	Low risk	None missing at day 1 and week 1 and only 3 missing at FU (in NSAID group)
Selective reporting (reporting bias)	Low risk	Only visual acuity missing
Other bias	Low risk	None detected

Simone 1999

Methods	RCT Compares ketorolac tromethamine 0.5% to prednisolone acetate 1% Outcome measures: inflammation and pain Follow-up: 1, 7 and 28 days postoperatively
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias)	Low risk	"double blind"
Blinding of outcome assessment (detection bias)	Low risk	"double blind"
Incomplete outcome data (attrition bias)	Low risk	apparently no dropouts
Selective reporting (reporting bias)	Low risk	Only flare missing
Other bias	Low risk	None detected

Solomon 2001

Methods	RCT Compares the effect of ketorolac tromethamine 0.5% to rimexolone 1% Outcome measures: inflammation Follow-up: 1, 4, 7 and 30 days postoperatively
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Low risk	"medications were given in identical bottles"
Blinding of participants and personnel (performance bias)	Low risk	"treatment was bmasked to both patient and investigator""medications were given in identical bottles"
Blinding of outcome assessment (detection bias)	Low risk	"treatment was bmasked to both patient and investigator"
Incomplete outcome data (attrition bias)	High risk	drop out: 4/18 in NSAID and 3/20 in the steroid group
Selective reporting (reporting bias)	Low risk	Only cme missing, but poor reporting
Other bias	Low risk	None detected

Wang 2013

Methods	RCT comparing macular thickness by OCT at 1 and 2 months postoperatively in patients randomized to bromfenac 1 or 2 months or fluorometholone for 1 month or dexamethasone for 1 month
Participants	Patients with age-related cataract undergoing phacoemulsification
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Random numbers table"
Allocation concealment (selection bias)	High risk	Same physician served as the medical monito and assigned one of the drugs to each patient, open label
Blinding of participants and personnel (performance bias)	High risk	open label
Blinding of outcome assessment (detection bias)	High risk	open label
Incomplete outcome data (attrition bias)	High risk	30% drop out for outcomes beyond one week, 0% for flare 1 week and IOP post
Selective reporting (reporting bias)	Low risk	Only cells missing
Other bias	Low risk	None detected

Wang 2013 B

Methods	
Participants	
Interventions	
Outcomes	
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Random numbers table"
Allocation concealment (selection bias)	High risk	Same physician served as the medical monito and assigned one of the drugs to each patient, open label
Blinding of participants and personnel (performance bias)	High risk	open label
Blinding of outcome assessment (detection bias)	High risk	open label
Incomplete outcome data (attrition bias)	High risk	30% drop out for outcomes beyond one week, 0% for flare 1 week and IOP post
Selective reporting (reporting bias)	Low risk	Only cells missing
Other bias	Low risk	None detected

Wielders 2018

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention: Topikal (øjendråbe) behandling med steroid-præparat ● *Mean age (sd)*: 71.23 (8.73) ● *No. of males (%)*: 46.4 Control: Topikal behandling med NSAID-præparat ● *Mean age (sd)*: 69.70 (8.94) ● *No. of males (%)*: 45.9 Overall ● *Mean age (sd)*: ● *No. of males (%)*: **Included criteria:** The trial included nondiabetic patients 21 yearsor older who required regular phacoemulsification cataract sur-gery in at least 1 eye. **Excluded criteria:** Patients were excluded if theyhad previous CME, any macular pathology that could influence vi-sual acuity, previous intraocular inflammation or uveitis, retinalvein occlusion, posttraumatic cataract, progressive glaucoma,intraocular pressure (IOP) of 25 mm Hg or higher, previoussteroid-induced IOP elevation, pseudoexfoliation syndrome, orFuchs endothelial dystrophy in the study eye. Furthermore, pa-tients were excluded if they had intraocular surgery in the studyeye. Patients who used topical NSAIDs, corticosteroids, antiglau-comatous medication, or high-dose systemic corticosteroids atthe time of screening were excluded, as were patients who receivedn intravitreal injection of bevacizumab or ranibizumab in thestudy eye in the previous 6 weeks, an intravitreal injection of afli-bercept in the previous

	10 weeks, or an intraocular or periocularcorticosteroid injection in the previous 4 months. Finally, patients were excluded if there was a contraindication to the use of anyinvestigation drug **Pretreatment:**
Interventions	**Intervention Characteristics** Intervention: Topikal (øjendråbe) behandling med steroid-præparat ● *Description*: Dexamethasone disodium phosphate 0.1% ● *Duration of intervention*: 1 uge ● *Dose*: 4 dråber dgl. gn. 1. uge. Derefter 1 dråbe mindre hver dag i følgende 2. uge. Start 2 dage præop. ● *Follow-up time after EoT*: 10 uger Control: Topikal behandling med NSAID-præparat ● *Description*: Bromfenac 0.09% ● *Duration of intervention*: 2 uger ● *Dose*: 2 dråber dgl. i 2 uger. Start 2 dage præop. ● *Follow-up time after EoT*: 10 uger
Outcomes	*Cystoidt makulaødem* ● **Outcome type**: DichotomousOutcome *Slutvisus (Visus postop)* ● **Outcome type**: ContinuousOutcome *Risikomål: Intraokulær trykstigning* ● **Outcome type**: ContinuousOutcome *Samlet antal adverse events (som defineret af studie)* ● **Outcome type**: DichotomousOutcome
Notes	*NKR 04 Grå stær* on 15/04/2019 23:34 **Select** Erratum: J Cataract Refract Surg. 2018 Sep;44(9):1166. doi: 10.1016/j.jcrs.2018.08.001.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly allocated to 1 of 3 treatment groups in a 1:1:1 ratio. Stratified block randomization was performed per study center by a local investigator using concealed online software B (ALEA, version 3.0, Formsvision BV) and a block size of 15 pa- tients."
Allocation concealment (selection bias)	Low risk	Quote: "in the posterior segment and received perioperative and/or postoperative antibiotics according to the standard of care in the participating study center. Patients were randomly allocated to 1 of 3 treatment groups in a 1:1:1 ratio. Stratified block randomization was performed per study center by a local investigator using concealed online software B (ALEA, version 3.0, Formsvision BV) and a block size of 15 pa- tients. Trial participants were unblinded for the allocated treat- ment. Patients in the bromfenac group received bromfenac 0.09% eyedrops (Yellox) twice"
Blinding of participants and personnel (performance bias)	Low risk	Quote: "Postoperative visits were performed 6 weeks and 12 weeks post- operatively and included a full ophthalmologic examination of the study eye, as reported above. Postoperative CDVA measurements and SD-OCT assessments were performed by a local investigator who was masked to the allocated study treatment." Judgement Comment: Trial participants were unblinded for the allocated treatment, however this had minimal influence on outcomes
Blinding of outcome assessment (detection bias)	Low risk	Quote: "Postoperative data analyses were performed with masking for the treatment groups." Judgement Comment: Assessments were performed by a local investigator who was masked
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: S. 435: Ingen statistisk forskel mellem grupperne på antal af dropouts eller årsager til dropouts. ITT analyser
Selective reporting (reporting bias)	Low risk	Quote: "a randomized controlled trial (RCT). The study protocol was approved by the local ethics com- mittees and national authorities of all participating study centers. The study procedures were performed" Judgement Comment: Protokol er tilgængelig og primær og sekundær outcomes er rapporteret.
Other bias	Low risk	Judgement Comment: The study appears to be free from other sources of bias.

Ylinen 2018

Methods	**Study design:** Randomized controlled trial **Study grouping:**
Participants	**Baseline Characteristics** Intervention: Topikal (øjendråbe) behandling med steroid-præparat ● *Mean age (sd)*: 77.1 (0.8) ● *No. of males (%)*: 46 Control: Topikal behandling med NSAID-præparat ● *Mean age (sd)*: 76.0 (0.7) ● *No. of males (%)*: 38 Overall ● *Mean age (sd)*: ● *No. of males (%)*:

	Included criteria: The study subjects were aged 60−90 years and were eligible for cataractsurgery under the Current Care Guide-lines of Cataract Surgery of the Finnish Medical Society, Duodecim (updatedin year 2013). **Excluded criteria:** Exclusion criteria of the study wereprior or active wet AMD, retinal vein/artery occlusion, retinal detachment,retinal necrosis, vitritis/endophthalmi-tis, vitreous haemorrhage, retinal phle-bitis or optic neuritis, previousintraocular procedures (including fun-dus laser photocoagulation), plannedanti-vascular endothelial growth factortreatments, myopia above6.0 diop-tres, alcohol abuse, hypothyroidismwith thyroid-stimulating hormone(TSH) above physiological range, con-tinuous use of anti-inflammatory drugsand sensitivity to any of the medica-tions used in the operation or postop-eratively. Intraoperative complicationssuch as iris prolapse, use of sutures orposterior capsule tear, failure to attendthe postoperative control visit at282 days and failure to use thepostoperative anti-inflammatory medi-cation as prescribed were criteria forexclusion. **Pretreatment:**
Interventions	**Intervention Characteristics** Intervention: Topikal (øjendråbe) behandling med steroid-præparat ● *Description*: Monopex, DEX phosphate1 mg/ml ● *Duration of intervention*: 3 uger ● *Dose*: 1 dråbe x 3 dgl. ● *Follow-up time after EoT*: 1 uge Control: Topikal behandling med NSAID-præparat ● *Description*: NSAID(Voltaren Ophtha, DICL sodium1 mg/ml ● *Duration of intervention*: 3 uger ● *Dose*: 1 dråbe x 3 dgl ● *Follow-up time after EoT*: 1 uge
Outcomes	*Cystoidt makulaødem* ● **Outcome type**: DichotomousOutcome *Slutvisus (Visus postop)* ● **Outcome type**: ContinuousOutcome *Risikomål: Intraokulær trykstigning* ● **Outcome type**: ContinuousOutcome *Samlet antal adverse events (som defineret af studie)* ● **Outcome type**: DichotomousOutcome
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Judgement Comment: the method used to generate the randomisation sequence is not described
Allocation concealment (selection bias)	Unclear risk	Quote: "After the cataract operation, the research technician ran- domized the operated patient into a study group and distributed the marked envelopes accordingly." Judgement Comment: Insufficient information about concealment
Blinding of participants and personnel (performance bias)	Low risk	Quote: "The drug pipettes were covered with tape by hospital pharmacy and put into marked envelopes. After the cataract operation, the research technician ran- domized the operated patient into a study group and distributed the marked envelopes accordingly. The blinding was uncovered after the data was analyzed."
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "Best-corrected visual acuity (BCVA) was preoperatively evaluated by the referring ophthalmologist and postop-eratively with an autorefractometer" Judgement Comment: det er uklart hvem der er outcome assessor postoperatively
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Missing outcome data balanced across intervention groups with similar reasons
Selective reporting (reporting bias)	Low risk	Judgement Comment: Ingen protokol tilgængelig. Rapporterer samtlige af vores outcomes.
Other bias	Low risk	Quote: "data base for analysis. Patients A total of 224 eyes of 214 patients scheduled for cataract surgery were enrolled between January 2016 and October 2016. Thirteen patients did not want" Judgement Comment: All outcomes reported per eye

Footnotes

Characteristics of excluded studies

Akcay 2012

Reason for exclusion	Retrospective observational study describing the changes in macular thickness. Does not examine the prophylactic role or NSAID and/or steroids in PCME

Allen 2006

Reason for exclusion	Commentary on Negi 2006.

Almeida 2008

Reason for exclusion	RCT. Compares steroids to steroid + NSAID. Steroid dosing the same in control and intervention group. Does not compare steroids to placebo or NSAID without steroids.

Almeida 2012

Reason for exclusion	RCT compares ketorolac or nepafenac to placebo. No evaluation of the effect of steroids

Altinas 2005

Reason for exclusion	Restrospective case report. Does not examine the prophylactic role or NSAID and/or steroids in PCME

Aptel 2017

Reason for exclusion	Wrong comparator

Arcieri 2005

Reason for exclusion	RCT. Evaluates the effect of bimatoprost, latanoprost or travoprost on blood-aqueous changes. Does not examine the prophylactic role of NSAID and/or steroids in PCME

Baiza-Duran 2007

Reason for exclusion	RCT. Compares the effect of meloxicam and diclofenac in postoperative inflammation. Does not examine the prophylactic role of steroids

Bannale 2012

Reason for exclusion	Appears not to be an RCT. Email sendt to author, but no reply.

Boscia 2017

Reason for exclusion	Wrong patient population

Campa 2018

Reason for exclusion	Wrong study design

Campochiaro 2017

Reason for exclusion	Wrong patient population

Chatziralli 2017

Reason for exclusion	Wrong intervention

Choulidou 2014

Reason for exclusion	Wrong outcomes

Cunha 2013

Reason for exclusion	Wrong comparator

Czajka 2016

Reason for exclusion	Wrong patient population

Danni 2019

Reason for exclusion	Wrong patient population

Dave 2014

Reason for exclusion	Wrong study design

Duan 2017

Reason for exclusion	Wrong comparator

Duong 2015

Reason for exclusion	Wrong patient population

ElGharbawy 2018

Reason for exclusion	Wrong patient population

Fierro 2016

Reason for exclusion	Wrong outcomes

Garg 2016

Reason for exclusion	Wrong study design

Grzybowski 2016

Reason for exclusion	Wrong study design

Grzybowski 2016a

Reason for exclusion	Wrong study design

Guo 2015

Reason for exclusion	No new studies included in the systematic review since last NKR

Hosseini 2016

Reason for exclusion	Wrong comparator

Hutcheson 2014

Reason for exclusion	Wrong intervention

Ilveskoski 2018

Reason for exclusion	No new studies included in the systematic review since last NKR

Jones 2013

Reason for exclusion	Wrong comparator

Jung 2015

Reason for exclusion	Wrong study design

Juthani 2017

Reason for exclusion	No new studies included in the systematic review since last NKR

Kessel 2014

Reason for exclusion	No new studies included in the systematic review since last NKR

Kherani 2016

Reason for exclusion	Wrong intervention

Kim 2015

Reason for exclusion	No new studies included in the systematic review since last NKR

Kim 2015a

Reason for exclusion	Wrong study design

Kohnen 2017

Reason for exclusion	Wrong study design

Lane 2013

Reason for exclusion	Wrong intervention

Lim 2016

Reason for exclusion	No new studies included in the systematic review since last NKR

Lim 2016a

Reason for exclusion	Wrong study design

Mamalis 2018

Reason for exclusion	Wrong study design

McCafferty 2017

Reason for exclusion	Wrong intervention

Medic 2017

Reason for exclusion	Wrong patient population

Merkoudis 2014

Reason for exclusion	Wrong comparator

Modi 2014

Reason for exclusion	Wrong comparator

Olson 2017

Reason for exclusion	Wrong outcomes

Pleyer 2013

Reason for exclusion	Wrong study design

Pollack 2017

Reason for exclusion	Wrong patient population

Quintana 2014

Reason for exclusion	No new studies included in the systematic review since last NKR

Rajpal 2013

Reason for exclusion	Wrong comparator

Ramakrishnan 2015

Reason for exclusion	Wrong comparator

Russo 2013

Reason for exclusion	Wrong study design

Sahu 2015

Reason for exclusion	Wrong intervention

Sekimoto 2014

Reason for exclusion	Wrong patient population

Sheppard 2016

Reason for exclusion	Wrong study design

Silverstein 2014

Reason for exclusion	Wrong outcomes

Singh 2017

Reason for exclusion	Wrong patient population

Singh 2017a

Reason for exclusion	Wrong patient population

Stock 2018

Reason for exclusion	Wrong comparator

Ticly 2014

Reason for exclusion	Wrong intervention

Toyos 2019

Reason for exclusion	Wrong comparator

Trattler 2017

Reason for exclusion	Wrong comparator

Turan Vural 2014

Reason for exclusion	Wrong comparator

Tzelikis 2015

Reason for exclusion	Wrong comparator

Walters 2014

Reason for exclusion	Wrong comparator

Wang 2013a

Reason for exclusion	Wrong study design

Weber 2013

Reason for exclusion	Wrong comparator

Wielders 2015

Reason for exclusion	No new studies included in the systematic review since last NKR

Wielders 2017

Reason for exclusion	No new studies included in the systematic review since last NKR

Wielders 2018a

Reason for exclusion	Wrong patient population

Ylinen 2018a

Reason for exclusion	Wrong comparator

Zaczek 2014

Reason for exclusion	Wrong intervention

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Reason for exclusion	Wrong comparator

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Reason for exclusion	Wrong comparator

Footnotes

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Holzer 2002

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Laurell 2002

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Missotten 2001

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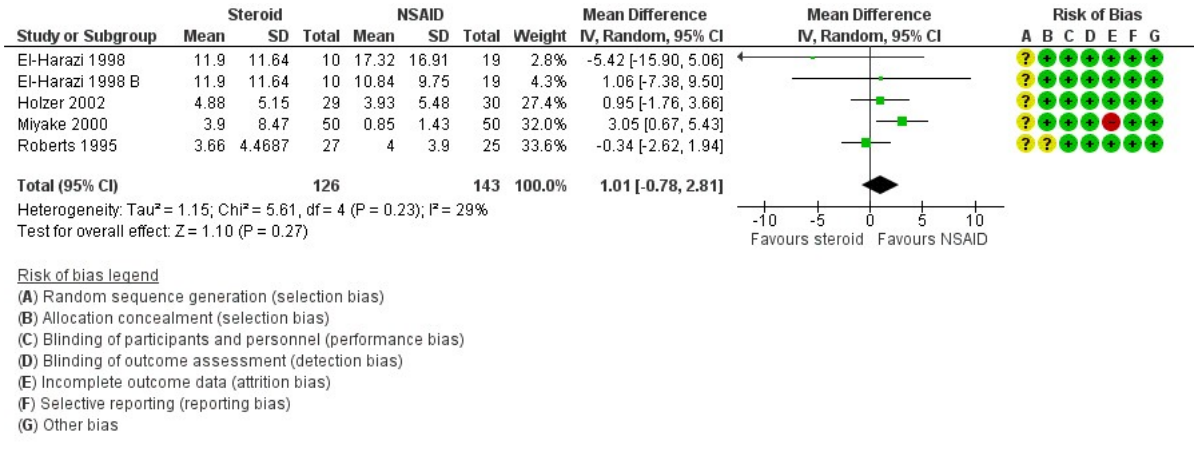
Data and analyses

1 Steroids vs. NSAIDs

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Cells day 2-8	5	269	Mean Difference (IV, Random, 95% CI)	1.01 [-0.78, 2.81]
1.2 Flare day 2-8	13	931	Mean Difference (IV, Random, 95% CI)	6.88 [3.26, 10.50]
1.3 Cystoid macular oedema	10	1253	Risk Ratio (M-H, Random, 95% CI)	3.70 [2.37, 5.78]
1.5 Visus postop	8	1074	Mean Difference (IV, Random, 95% CI)	0.02 [-0.00, 0.04]
1.6 IOP longest FU	17	1174	Mean Difference (IV, Random, 95% CI)	0.43 [-0.00, 0.86]
1.7 Samlet antal personer med adverse events (som defineret af studie)	18	1961	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.91, 1.32]

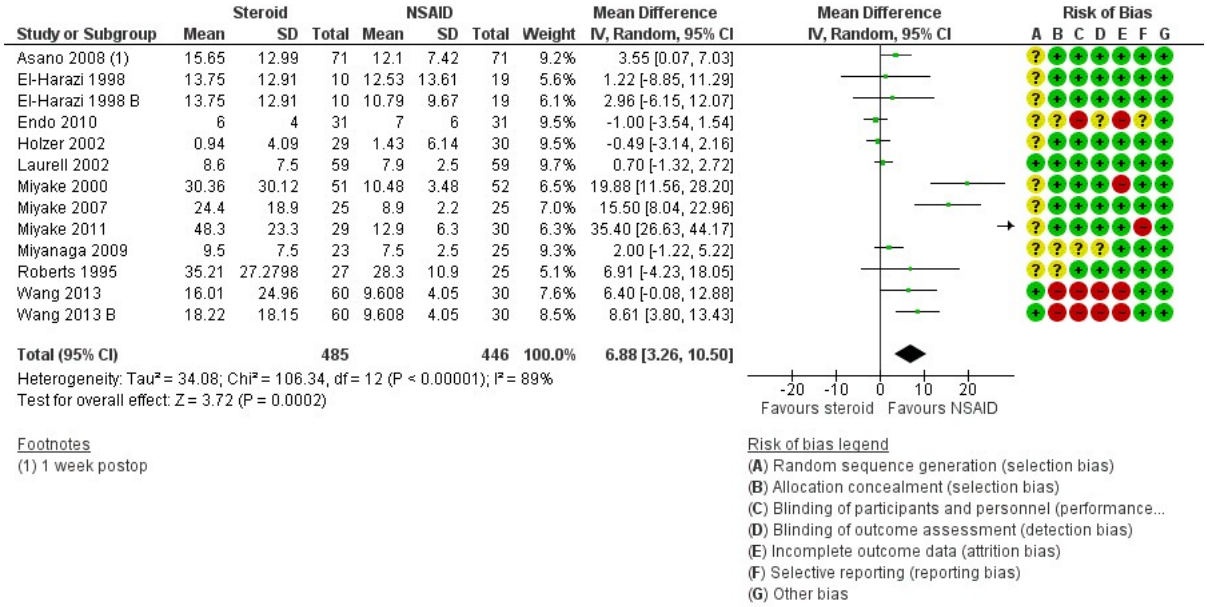
Figures

Figure 1 (Analysis 1.1)



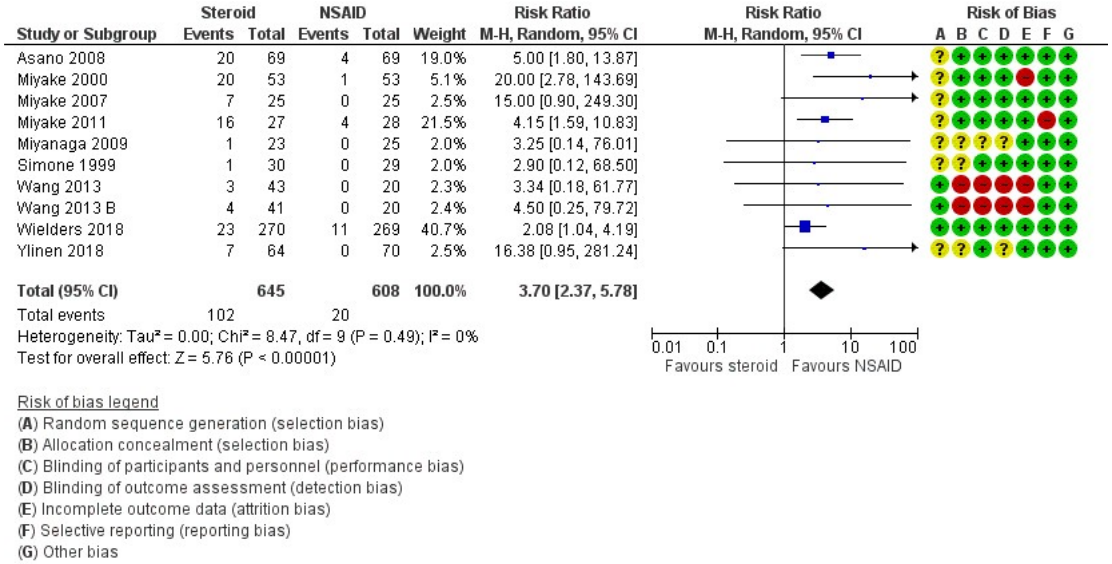
Forest plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.1 Cells day 2-8.

Figure 2 (Analysis 1.2)



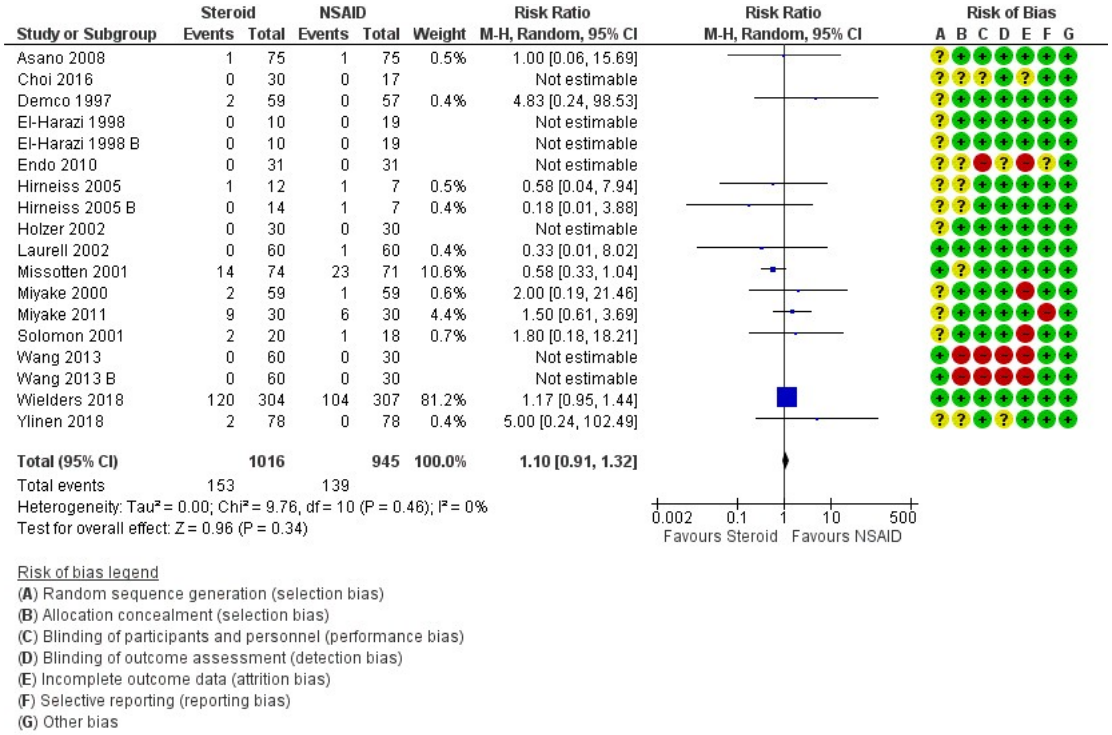
Forest plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.2 Flare day 2-8.

Figure 3 (Analysis 1.3)



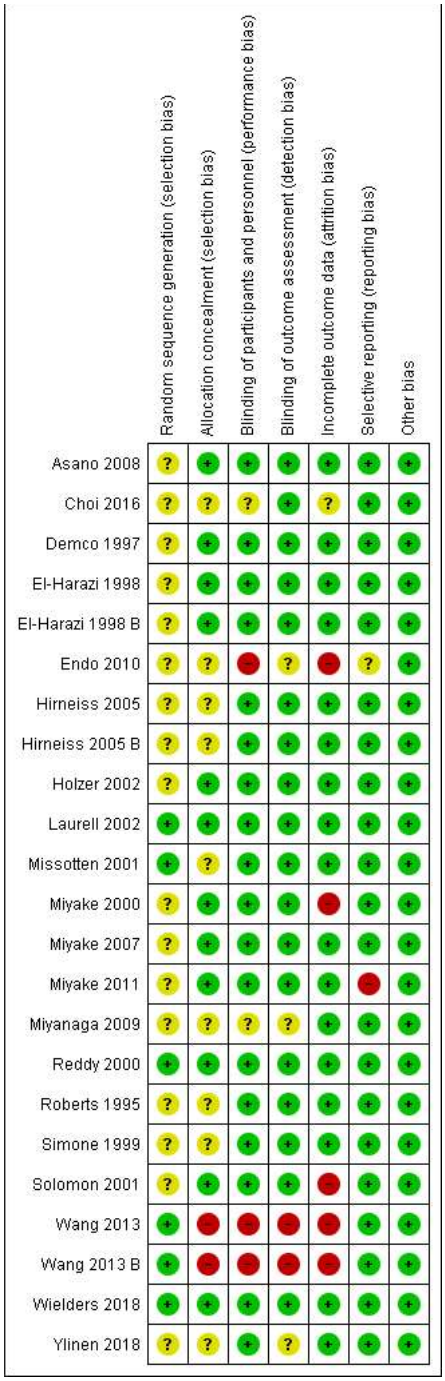
Forest plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.3 Cystoid macular oedema.

Figure 4 (Analysis 1.7)



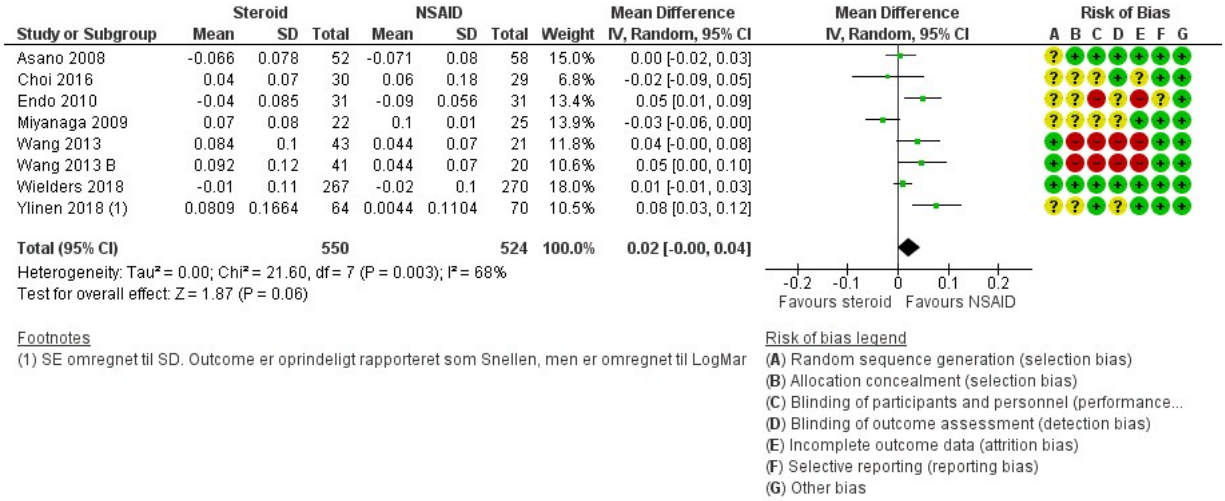
Forest plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.7 Samlet antal personer med adverse events (som defineret af studie).

Figure 5



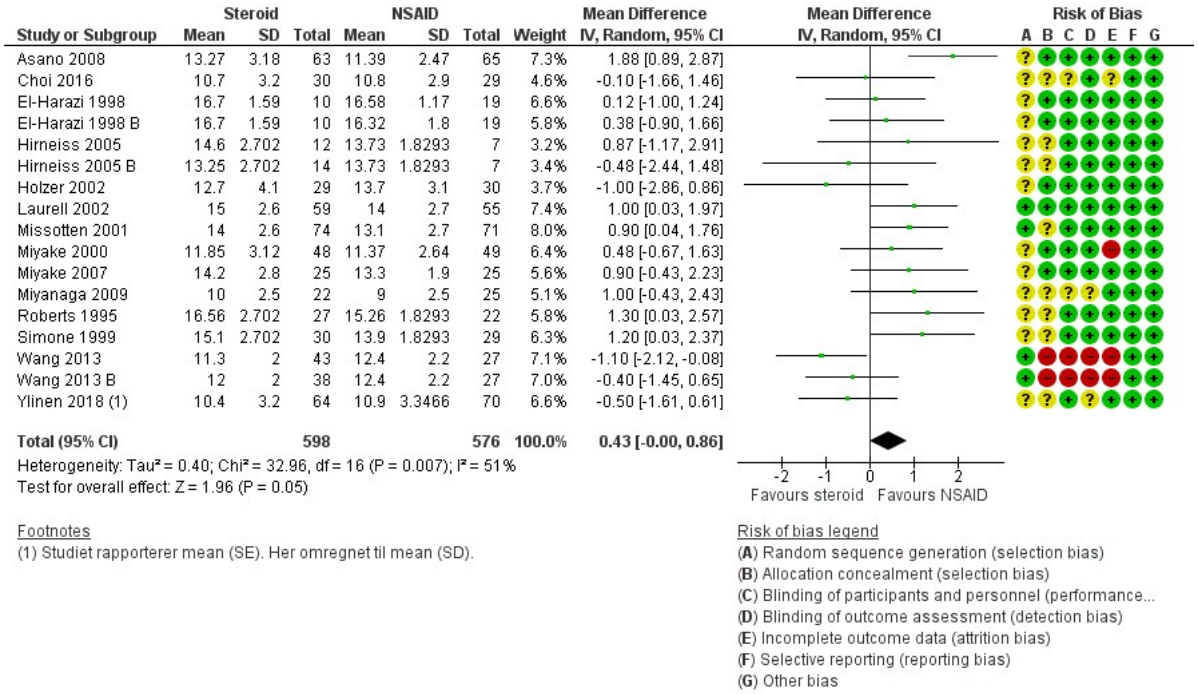
Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 6 (Analysis 1.5)



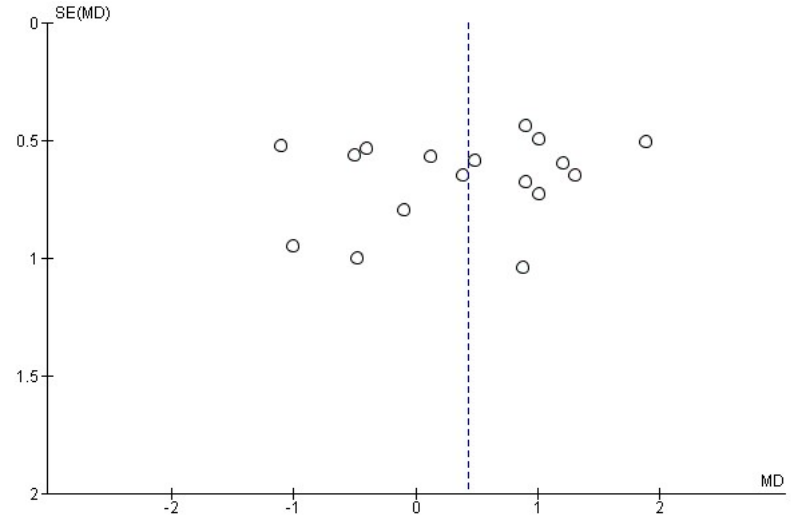
Forest plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.5 Visus postop.

Figure 7 (Analysis 1.6)



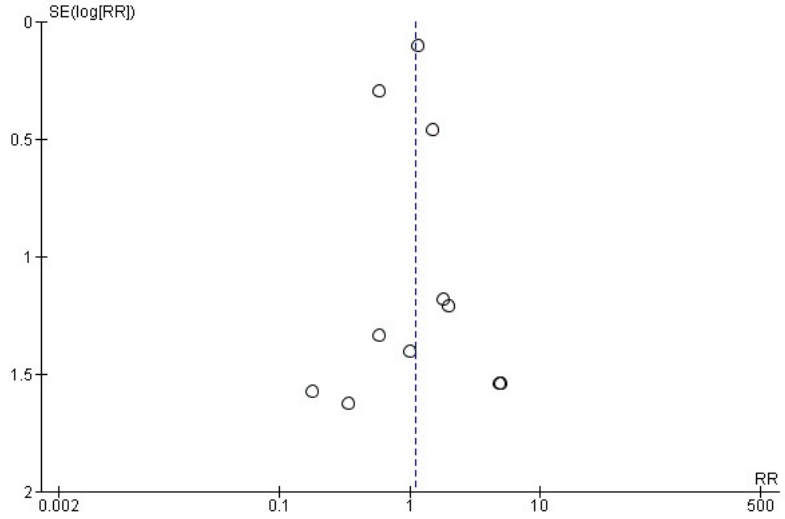
Forest plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.6 IOP longest FU.

Figure 8 (Analysis 1.6)



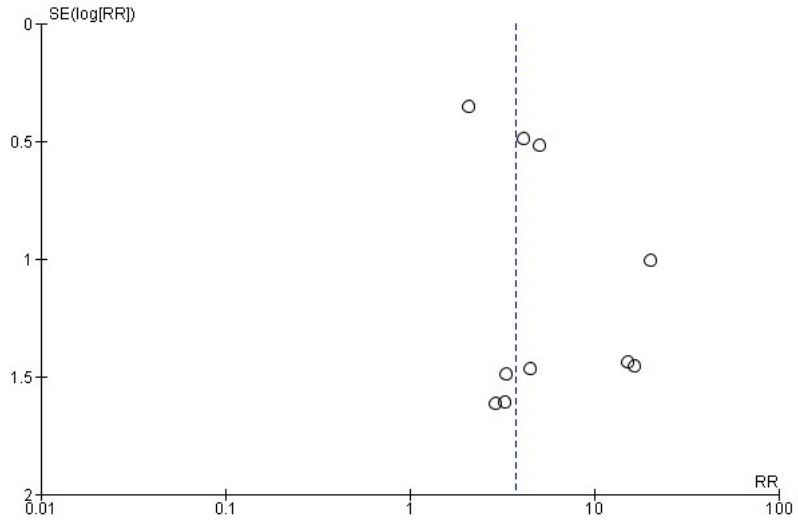
Funnel plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.6 IOP longest FU.

Figure 9 (Analysis 1.7)



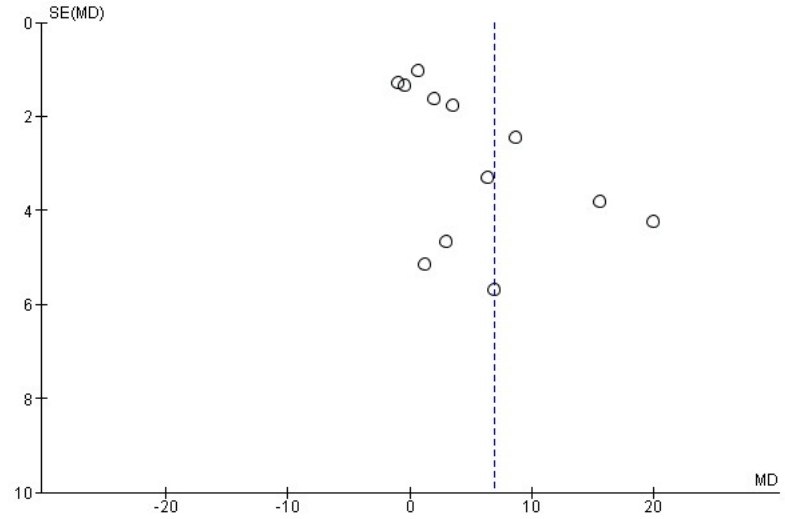
Funnel plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.7 Samlet antal personer med adverse events (som defineret af studie).

Figure 10 (Analysis 1.3)



Funnel plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.3 Cystoid macular oedema.

Figure 11 (Analysis 1.2)



Funnel plot of comparison: 1 Steroids vs. NSAIDs, outcome: 1.2 Flare day 2-8.