[Intervention] for [health problem]

Review information

Authors

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Citation example: [Empty name], DHaMA. [Intervention] for [health problem]. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Contact person

Sundhedsstyrelsen

What's new

Date / Event	Description

History

Date / Event	Description

Characteristics of studies

Characteristics of included studies

Ho 2010

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**

Participants	**Baseline Characteristics** intervention control **Included criteria:** adult patients with a minimum 12-monthhistory of psoriasis who attended the dermatologyoutpatient department at one of two hospitals.‡ 18 years. chronic plaque psoriasis. ‡ 20% of body surface areaAll patients agreed to cease taking high-potencytopical corticosteroids, phototherapy, systemic therapiesand TCM 4 weeks before and throughout the study.Useof moderate potency topical corticosteroids, vitamin Danalogues, keratolytics and coal tar were also ceased2 weeks before and throughout the study. Only fluocinolone0.0125% cream and aqueous cream werepermitted during the study. **Excluded criteria:** renal or liver impairment, active infection,immunosuppression or other serious concomitant illness. Pregnant and lactating women were excluded,and others agreed to take appropriate contraceptiveprecautions. **Pretreatment:** There were no significant differencesin age or gender between the groups.
Interventions	**Intervention Characteristics** intervention control
Outcomes	*PDI* ● **Outcome type**: ContinuousOutcome ● **Measure names**: ["Baseline", "6 month"] ● **Reporting**: Fully reported ● **Scale**: PDI ● **Range**: ? ● **Direction**: Lower is better ● **Data value**: Change from baseline
Identification	**Sponsorship source:** unknown **Country:** China **Setting:** outpatients climic **Comments:** **Authors name:** S. G. Y. Ho **Institution:** Division of Dermatology, Department of Medicine, University of Hong Kong, Hong Kong, China **Email:** hhlchan@hku.hk **Address:** Dr Henry Chan, 13/F Club Lusitano, 16, Ice House Street,Central, Hong Kong, China

Notes	*Birgitte Holm Petersen* on 04/09/2015 18:55 **Continuous Outcomes** Det er KUN PDII vi skal bruge. Derfor det eneste outcomePDI: Ikke helt tydeligt hvilken scala der bruges. Henviser til en reference hvor jeg ikke kan se fuldtekst. *Birgitte Holm Petersen* on 04/09/2015 18:58 **Baseline Characteristics** ingen tabel! *Jette Skiveren* on 15/09/2015 21:59 **Study Design** der er 3 grupper: MTX, TCM og placebo *Jette Skiveren* on 15/09/2015 22:19 **Continuous Outcomes** Control ssvarer til TCM gruppen. Placebogruppen ikke beskrevet i denne tabel

Risk of bias table

Bias	Authors' judgement	Support for judgement
Blinding of participants and personnel All outcomes	High risk	Judgement Comment: dem der vurderer effekt af behandlingen er blindede, men ptt ved om de enten får MTX eller TCM/placebo
Blinding of participants and personnel Livskvalitet	High risk	Judgement Comment: dem der vurderer effekt af behandlingen er blindede, men ptt ved om de enten får MTX eller TCM/placebo
Blinding of outcome assessors All outcomes	Low risk	Judgement Comment: Assessors er blindede

Blinding of outcome assessors Livskvalitet	Low risk	Judgement Comment: Assessors er blindede
Incomplete outcome data All outcomes	Low risk	Judgement Comment: Markant frafald i TCM og placebo gruppe - men kan ses som udtryk for manglende effekt af behandlingen
Incomplete outcome data Livskvalitet	High risk	Judgement Comment: □Markant frafald i TCM og placebo gruppe - men kan ses som udtryk for manglende effekt af behandlingen
Selective outcome reporting	Low risk	
Other sources of bias	Low risk	
Allocation concealment	Low risk	Quote: "Randomiza- tion was carried out by an investigator drawing random cards marked A, B or C to represent each of the different treatment groups. There were" Judgement Comment: Jeg mener trods alt at den er lav

Revicki 2008

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** intervention control **Included criteria:** Eligible patients were > 18 years of age; had moderateto severe chronic plaque psoriasis (defined by > 10% bodysurface area involvement and PASI score of > 10 at baseline);and had a clinical diagnosis of psoriasis for > 1 year and stableplaque psoriasis for ‡ 2 months before screening and at baselinevisits, as determined by medical history interviews. Allpatients were naı¨ve to TNF-antagonist therapies and to MTX.Patients had to have been able to self-inject medication orhave a qualified person available who could inject for them. **Excluded criteria:** **Pretreatment:** None
Interventions	**Intervention Characteristics** intervention control

Outcomes	*PDI* ● **Outcome type**: ContinuousOutcome ● **Measure names**: ["Baseline", "6 month"] *DLQI total* ● **Outcome type**: ContinuousOutcome ● **Measure names**: ["Baseline", "6 month"] ● **Reporting**: Fully reported ● **Scale**: DLQI ● **Range**: 0-30 ● **Direction**: Lower is better ● **Data value**: Change from baseline
Identification	**Sponsorship source:** funded by a research grant from AbbottLaboratories, Abbott Park, IL, USA **Country:** **Setting:** **Comments:** **Authors name:** D. Revicki, M.K. Willian,* J.-H. Saurat, K.A. Papp, J.-P. Ortonne,§ C. Sexton and A. Camez **Institution:** Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD 20814, U.S.A. **Email:** dennis.revicki@unitedbiosource.com **Address:**
Notes	*Jette Skiveren* on 16/09/2015 23:39 **Study Design** Tree study arms:adalimumabMTXplacebo *Jette Skiveren* on 16/09/2015 23:45 **Intervention Characteristics** Se pre treatment *Jette Skiveren* on 16/09/2015 23:50 **Continuous Outcomes** Jeg antager at interventionen er MTX vs placebo.Der mangler data efter 6 mdr for DQLI, placebo 9% og MTX 2% *Jette Skiveren* on 17/09/2015 16:47 **Baseline Characteristics**

	Ingen adgang til modulet for Jette

Risk of bias table

Bias	Authors' judgement	Support for judgement
Blinding of participants and personnel Livskvalitet	Low risk	Judgement Comment: The MTXgroup received MTX (7.5–25-mg) capsule(s) by mouth onceweekly from baseline (week 0) to week 15 plus two placeboinjections sc at baseline (week 0), followed by one placeboinjection sc eow from week 1 to week 15. The placebo groupreceived placebo injections sc at baseline (week 0), followedby one placebo injection sc eow and placebo capsule(s) bymouth once weekly from baseline (week 0) to week 15.
Blinding of participants and personnel All outcomes	Low risk	Judgement Comment: □double-blind, doubledummy, placebo-controlled
Blinding of outcome assessors All outcomes	Low risk	
Blinding of outcome assessors Livskvalitet	Low risk	
Incomplete outcome data All outcomes	Low risk	
Incomplete outcome data Livskvalitet	Low risk	
Selective outcome reporting	Low risk	
Other sources of bias	Low risk	
Sequence Generation	Low risk	Judgement Comment: Randomization was completed througha central computer-generated scheme stratified by centre, withblock sizes of four.
Allocation concealment	Low risk	Judgement Comment: Patient numbers were centrally assignedby an interactive voice-response system in consecutive order.

Footnotes

Characteristics of excluded studies

Berbis 1989

Reason for exclusion	Wrong study design

Flytstrom 2008

Reason for exclusion	Wrong comparator

Gumusel 2011

Reason for exclusion	Wrong comparator

Heydendael 2003

Reason for exclusion	Wrong comparator

Sandhu 2003

Reason for exclusion	Wrong comparator

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables

References to studies

Included studies

Ho 2010

Ho,S. G. Y.; Yeung,C. K.; Chan,H. H. L.. Methotrexate versus traditional Chinese medicine in psoriasis: a randomized, placebo-controlled trial to determine efficacy, safety and quality of life. Clinical and experimental dermatology 2010;35(Journal Article):717-722. [DOI: 10.1111/j.1365-2230.2009.03693.x]

Revicki 2008

Revicki,D.; Willian,M. K.; Saurat,J. H.; Papp,K. A.; Ortonne,J. P.; Sexton,C.; Camez,A.. Impact of adalimumab treatment on health-related quality of life and other patient-reported outcomes: results from a 16-week randomized controlled trial in patients with moderate to severe plaque psoriasis. The British journal of dermatology 2008;158(3):549-557. [DOI: BJD8236 [pii]]

Excluded studies

Berbis 1989

Berbis,P.; Geiger,J. M.; Vaisse,C.; Rognin,C.; Privat,Y.. BENEFIT OF PROGRESSIVELY INCREASING DOSES DURING THE INITIAL TREATMENT WITH ACITRETIN IN PSORIASIS. Dermatologica 1989;178(Journal Article):88-92. [DOI:]

Flytstrom 2008

Flytstrom,I.; Stenberg,B.; Svensson,A.; Bergbrant,I. M.. Methotrexate vs. ciclosporin in psoriasis: effectiveness, quality of life and safety. A randomized controlled trial. British Journal of Dermatology 2008;158(Journal Article):116-121. [DOI: 10.1111/j.1365-2133.2007.08284.x]

Gumusel 2011

Gumusel,M.; Ozdemir,M.; Mevlitoglu,I.; Bodur,S.. Evaluation of the efficacy of methotrexate and cyclosporine therapies on psoriatic nails: a one-blind, randomized study. Journal of the European Academy of Dermatology and Venereology 2011;25(Journal Article):1080-1084. [DOI: 10.1111/j.1468-3083.2010.03927.x]

Heydendael 2003

Heydendael,V. M. R.; Spuls,P. I.; Opmeer,B. C.; De Borgie,C. A. J. M.; Reitsma,J. B.; Goldschmidt,W. F. M.; Bossuyt,P. M. M.; Bos,J. D.; De Rie,M. A.. Methotrexate versus cyclosporine in moderate-to-severe chronic plaque psoriasis.. New England Journal of Medicine 2003;349(7):658-665. [DOI: http://dx.doi.org/10.1056/NEJMoa021359]

Sandhu 2003

Sandhu,K.; Kaur,I.; Kumar,B.; Saraswat,A.. Efficacy and safety of cyclosporine versus methotrexate in severe psoriasis: A study from north India. Journal of Dermatology 2003;30(Journal Article):458-463. [DOI:]

Studies awaiting classification

Ongoing studies

Other references

Additional references

Other published versions of this review

Classification pending references

Data and analyses

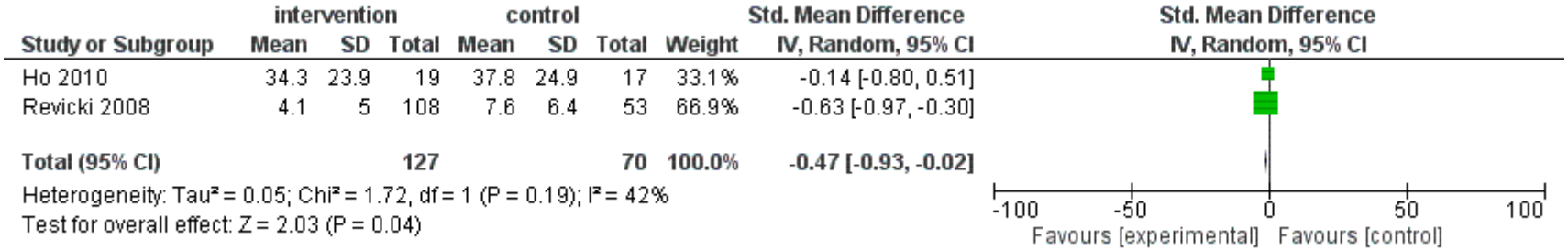
1 intervention vs control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 PDI	1	72	Mean Difference (IV, Fixed, 95% CI)	1.35 [-8.67, 11.38]
1.1.1 6 month	1	36	Mean Difference (IV, Fixed, 95% CI)	-3.50 [-19.49, 12.49]
1.1.2 Baseline	1	36	Mean Difference (IV, Fixed, 95% CI)	4.50 [-8.37, 17.37]
1.2 DLQI total	1	322	Mean Difference (IV, Fixed, 95% CI)	-2.78 [-4.24, -1.32]
1.2.1 6 month	1	161	Mean Difference (IV, Fixed, 95% CI)	-3.50 [-5.46, -1.54]
1.2.2 Baseline	1	161	Mean Difference (IV, Fixed, 95% CI)	-1.90 [-4.08, 0.28]

1.3 Livskvalitet	2	197	Std. Mean Difference (IV, Random, 95% CI)	-0.47 [-0.93, -0.02]

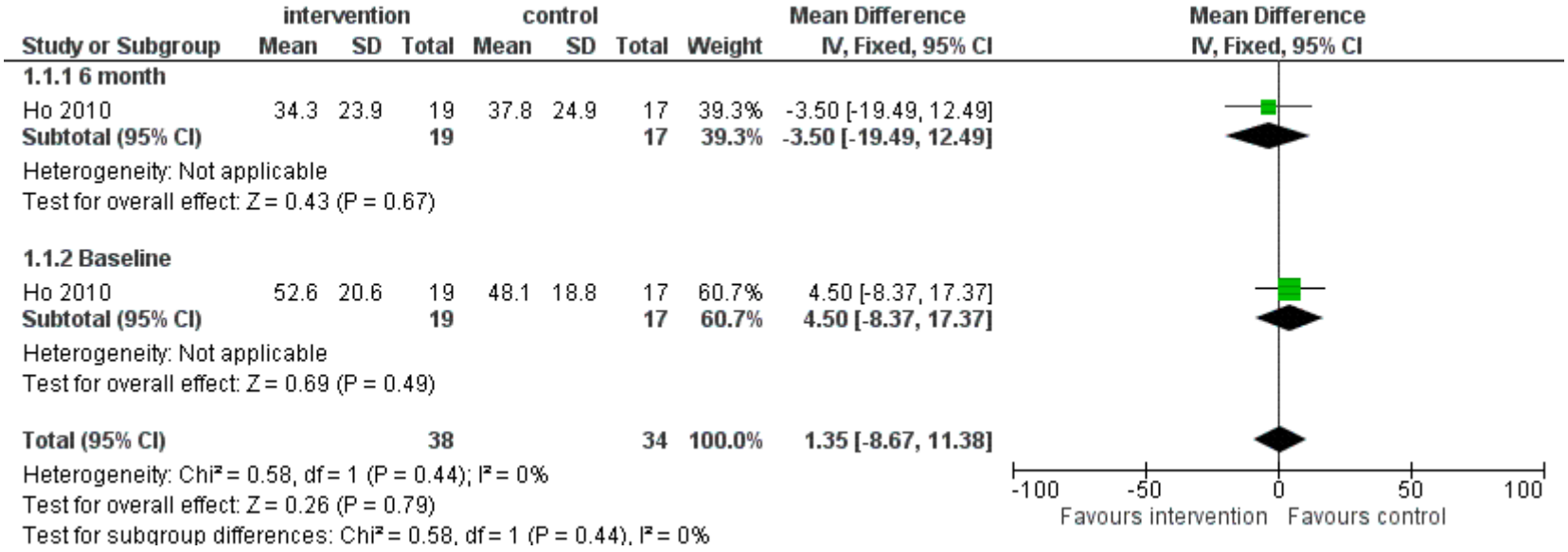
Figures

Figure 1 (Analysis 1.3)



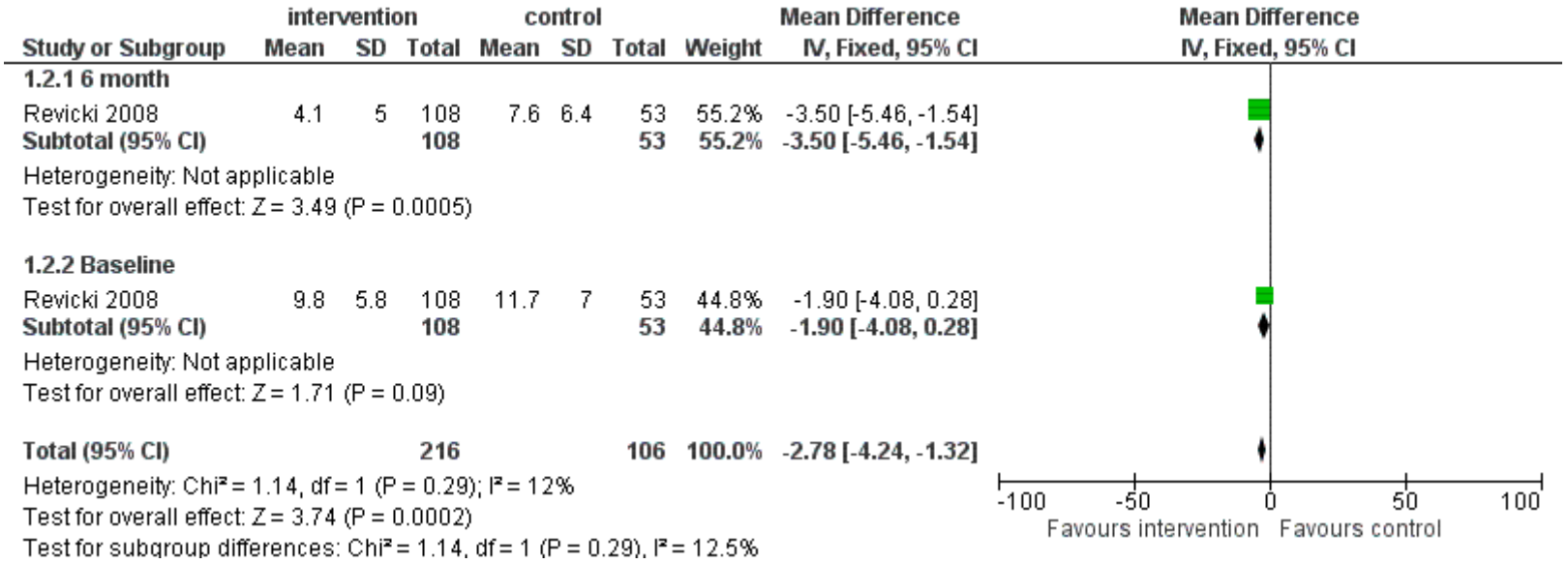
Forest plot of comparison: 1 intervention vs control, outcome: 1.3 Livskvalitet.

Figure 2 (Analysis 1.1)



Forest plot of comparison: 1 intervention vs control, outcome: 1.1 PDI.

Figure 3 (Analysis 1.2)



Forest plot of comparison: 1 intervention vs control, outcome: 1.2 DLQI total.

Appendices