[Intervention] for [health problem]

Review information

Authors

[Empty name][1], [Empty name][1]

[1][Empty affiliation]

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

Characteristics of studies

Characteristics of included studies

Predel 2013

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Males (%)*: 52.8 ● *Mean age (SD)*: 29.8 (10.5) ● *Symptom duration*: 246.5 (306.5) hours ● *Symptom characteristics (Pain at rest)*: 41.1 (17.0) Control ● *Males (%)*: 38.9 ● *Mean age (SD)*: 27.8 (15.2) ● *Symptom duration*: 248.4 (348.3) hours ● *Symptom characteristics (Pain at rest)*: 40.1 (16.9) **Included criteria:** The study population consisted of male and female sub-jects, aged 18 years and over with acute NP originatingfrom cervical joints and accompanying soft tissues. Painhad been present for at least 12 h and resulted in

	POM≥ 50 mm on a 100-mm visual analogue scale (VAS). **Excluded criteria:** Exclusion criteria included any neck pain that was at-tributable to an organic disease (e.g. prolapsed disc,inflammatory arthritis, neurological diseases, etc.), asassessed by the medical history, including previous andconcomitant diseases, and a neck examination and diag-nosis, any recent strains of the neck muscles, chronicneck pain defined as pain for 3 months or longer, anduse of pain medication within the 6 h precedingrandomization. **Pretreatment:** The control group tend to have more women and be older. This is not assumed to bias results.
Interventions	**Intervention Characteristics** Intervention ● *Description*: topical treatment with DDEA 1.16% gel (Voltaren® Schmerzgel® (German tradename), Voltaren® Emulgel® (European trade name),Novartis Consumer Health ● *Duration (weeks)*: 5 days ● *Number of treatments (total)*: 20 Control ● *Description*: Placebo gel (the same vehicle as for DDEA 1.16% gel without diclofenac ● *Duration (weeks)*: 5 days ● *Number of treatments (total)*: 20
Outcomes	*Smerte (Pain) End of treatment* ● **Outcome type**: ContinuousOutcome ● **Direction**: Lower is better *Smerte (Pain) 4-12 ugers follow-up* ● **Outcome type**: ContinuousOutcome ● **Direction**: Lower is better *Funktionsevne 4-12 ugers follow-up* ● **Outcome type**: ContinuousOutcome *Tilbage til arbejde 4-12 ugers follow-up* ● **Outcome type**: DichotomousOutcome *Sygefravær 4-12 ugers follow-up* ● **Outcome type**: DichotomousOutcome *Livskvalitet 4-12 ugers follow-up*

	● **Outcome type**: ContinuousOutcome *SAE (Serious adverse events) End of Treatment* ● **Outcome type**: DichotomousOutcome *Komplikationer End of Treatment* ● **Outcome type**: DichotomousOutcome *Frafald End of Treament* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** The study was funded by Novartis Consumer Health SA, Nyon, Switzerland.The medical writer was funded by Novartis Consumer Health SA, Nyon,Switzerland. The authors Agnes Hug and Ian Burnett are employees ofNovartis Consumer Health **Country:** Germany **Setting:** Three German(Cologne, Gilching and Essen) sports medicine practice clinic **Comments:** **Authors name:** Hans-Georg Predel **Institution:** Deutsche Sporthoschschule Köln, Köln, Germany. CRM clinical trials GmbH,Rheinbach, Germany. Internal Medicine and Sport, Essen,Germany. Novartis Consumer Health **Email:** predel@dshs-koeln.de **Address:** Deutsche Sporthoschschule Köln, Köln, Germany
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Novartis Pharmaceuticals Drug Supply Management pro- duced the randomization list, using a system that auto- mated the random assignment of treatment groups to randomization numbers.
Allocation concealment (selection bias)	Low risk	randomization data were kept strictly confidential until the time of unblinding and were not ac- cessible by anyone involved in the study,

Blinding of participants and personnel (performance bias)	Low risk	Subjects, investigator staff, persons performing all assessments, monitors and data analysts remained blinded to the identity of the treatment from the time of randomization until database lock,
Blinding of outcome assessment (detection bias)	Low risk	Patient reported outcomes; patients were blinded
Incomplete outcome data (attrition bias)	Low risk	100% follow-up. Lidt utroligt at der slet ingen blev screenet, som ikke opfyldte kriterier for deltagelse eller som ikke ønskede at deltage?
Selective reporting (reporting bias)	Low risk	All mentioned outcomes reported
Other bias	Unclear risk	Is it likely that no potential participants were screened without being included. Is it fair to state no conflicts of interests when employed by the medical company selling the gel?

Footnotes

Characteristics of excluded studies

Bronfort 2012

Reason for exclusion	Wrong comparator

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

References to studies

Included studies

Predel 2013

Predel,Hans-Georg; Giannetti,Bruno; Pabst,Helmut; Schaefer,Axel; Hug,Agnes M.; Burnett,Ian. Efficacy and safety of diclofenac diethylamine 1.16% gel in acute neck pain: a randomized, double-blind, placebo-controlled study.. BMC Musculoskeletal Disorders 2013;14(Journal Article):250. [DOI: http://dx.doi.org/10.1186/1471-2474-14-250]

Excluded studies

Bronfort 2012

Bronfort,G.; Evans,R.; Anderson,A. V.; Svendsen,K. H.; Bracha,Y.; Grimm,R. H.. Spinal manipulation, medication, or home exercise with advice for acute and subacute neck pain: a randomized trial. Annals of Internal Medicine 2012;156(1 Pt 1):1-10. [DOI: http://dx.doi.org/10.7326/0003-4819-156-1-201201030-00002]

Data and analyses

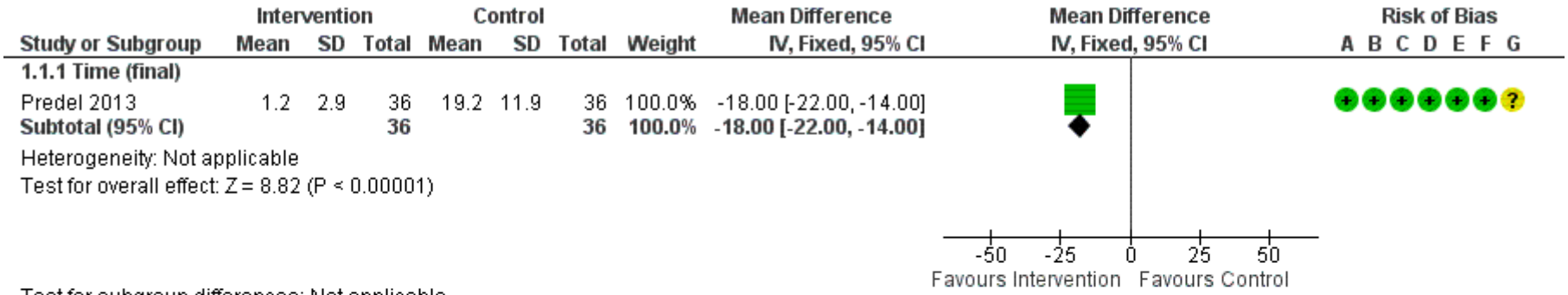
1 NSAID vs Ingen NSAID

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Smerte (Pain) End of treatment	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1.1 Time (final)	1	72	Mean Difference (IV, Fixed, 95% CI)	-18.00 [-22.00, -14.00]
1.2 Smerte (Pain) 4-12 ugers follow-up	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.3 Funktionsevne 4-12 ugers follow-up	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.4 Livskvalitet 4-12 ugers follow-up	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.5 Tilbage til arbejde 4-12 ugers follow-up	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.6 Sygefravær 4-12 ugers follow-up	0		Risk Ratio (IV, Fixed, 95% CI)	No totals

1.7 SAE (Serious adverse events) End of Treatment	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.7.1 Time	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.8 Komplikationer End of Treatment	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.8.1 Time	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.9 Frafald End of Treament	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.9.1 Time	1		Risk Ratio (IV, Fixed, 95% CI)	No totals

Figures

Figure 1 (Analysis 1.1)



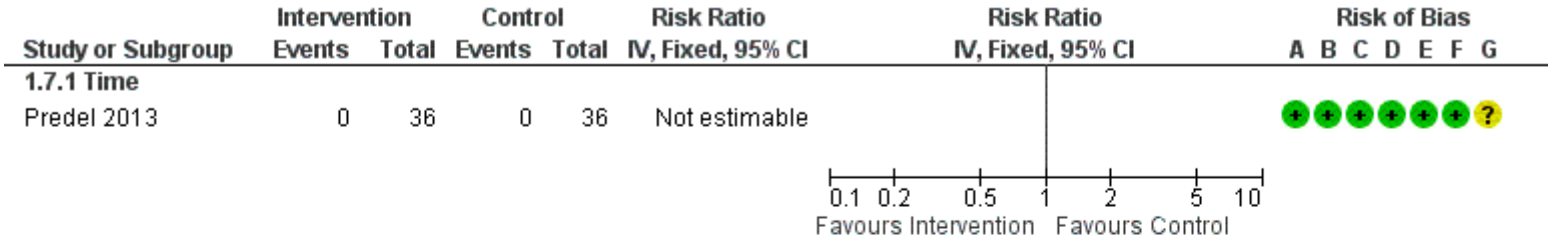
Test for subgroup differences: Not applicable

Risk of bias legend

(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

Forest plot of comparison: 1 Intervention vs Control, outcome: 1.1 Smerte (Pain) End of treatment.

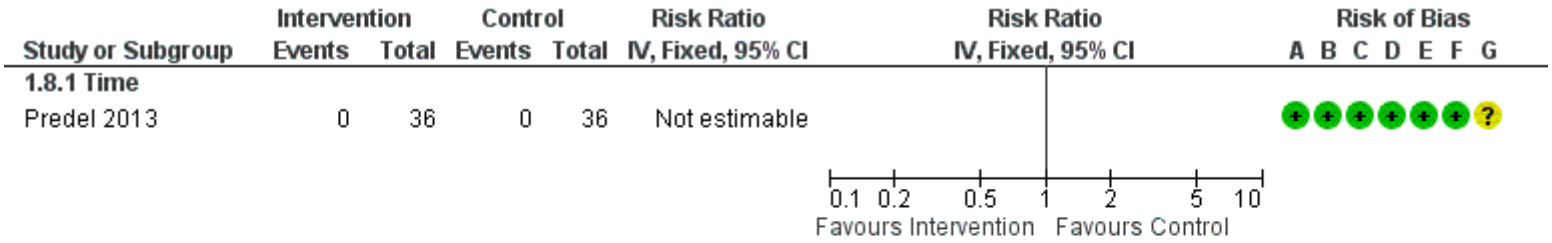
Figure 2 (Analysis 1.7)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 NSAID vs Ingen NSAID, outcome: 1.7 SAE (Serious adverse events) End of Treatment.

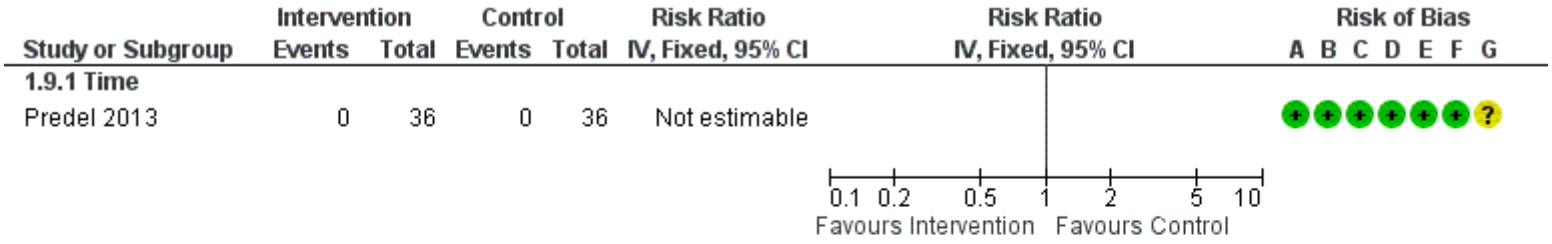
Figure 3 (Analysis 1.8)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 NSAID vs Ingen NSAID, outcome: 1.8 Komplikationer End of Treatment.

Figure 4 (Analysis 1.9)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 NSAID vs Ingen NSAID, outcome: 1.9 Frafald End of Treament.