Strømper versus ingen intervention for kronisk ødem

Review information

Authors

Sundhedsstyrelsen[1]

[1][Empty affiliation]

Citation example: S. Strømper versus ingen intervention for kronisk ødem. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Carvalho 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Crossover
Participants	**Baseline Characteristics** Intervention ● *Age mean (sd)*: ● *Number of Females*: 21 females ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic edema CEAP2*: ● *mobile/immobile*: ● *Main reason for chronic edema CEAP3*: ● *Number of males*: ● *Age range*: control ● *Age mean (sd)*: ● *Number of Females*: ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic edema CEAP2*: ● *mobile/immobile*: ● *Main reason for chronic edema CEAP3*: ● *Number of males*: ● *Age range*: Overall ● *Age mean (sd)*: 49.5 ● *Number of Females*: 21(42 legs) ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic edema CEAP2*: 6 ● *mobile/immobile*: ● *Main reason for chronic edema CEAP3*: 36 ● *Number of males*: 0 ● *Age range*: 32 to 72 **Included criteria:** edema and fatigue of the legs whichworsened during the day but improved with the rest andwithelevationofthelegsandpaininthelegs. **Excluded criteria:** varicose veins with CEAP classifications 4,5,and 6, difficulty walking, morbidobesity, orthopedic changes, and other diseases clinically evaluated which might cause the symptoms of the legs. **Pretreatment:** Non reported
Interventions	**Intervention Characteristics** Intervention ● *time interval*: 1 day ● *description of treatment with compression stockings*: In Assessment 2, the legs of the participants were againmeasured by volumetry at 7:00 a.m. and the stockings wereworn during the entire day with a further evaluation at 4:00p.m. (volumetric and analog pain scale). control ● *time interval*: 1 day ● *description of treatment with compression stockings*: Patients were their own control
Outcomes	*Ødem (edema) End of treatment, max 12 mdr.* ● **Outcome type**: ContinuousOutcome ● **Unit of measure**: Mililiter ● **Direction**: Lower is better ● **Data value**: Endpoint *Tilbagevendende sår (recurrent ulcer) End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better

	Tilbagevendende sår (recurrent ulcer) Follow up ≤ 12 mdr. ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better *Tilbagevendende sår (recurrent ulcer) Follow up 12 mdr.-24 mdr.* ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better *Smerter (bivirkning) (pain) End of treatment, max 12 mdr.* ● **Outcome type**: ContinuousOutcome ● **Direction**: Lower is better *Hudforandringer (skin changes) End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better *Livskvalitet (quality of life) End of treatment, max 12 mdr.* ● **Outcome type**: ContinuousOutcome *Roseninfektion (Erysipelas, Cellulitis) End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better *Roseninfektion (Erysipelas, cellulitis)Follow up ≥ 12 mdr.* ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better *Drop out End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome ● **Direction**: Lower is better
Identification	**Sponsorship source:** Non declared **Country:** Brazil **Setting:** Clinica Godoy **Comments:** **Authors name:** Carlos Alberto Carvalho **Institution:** Medical School in S˜ao Jos´e do Rio Preto, FAMERP, Avenida Constituic¸˜ao 1306, 15025-120 S˜ao Jos´edoRioPreto,SP,Brazil **Email:** godoyjmp@riopreto.com.br **Address:** Medical School in S˜ao Jos´e do Rio Preto, FAMERP, Avenida Constituic¸˜ao 1306, 15025-120 S˜ao Jos´edoRioPreto,SP,Brazil
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Consecutive patients were randomly assigned to two different groups where on the first day of the study one group followed Assessment 1 (Figure 1) and the other group followed Assessment 2" Judgement Comment: Randomization unclear
Allocation concealment (selection bias)	Unclear risk	Judgement Comment: "Consecutive patients" were randomized, formentlig til at forudse hvem der randomiseret til hvilken gruppe. Possible to foresee but as this is a crossover maybe not important
Blinding of participants and personnel (performance bias)	Unclear risk	-
Blinding of outcome assessment (detection bias)	Unclear risk	-
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: Nothing described but probably no dropouts with only two days
Selective reporting (reporting bias)	Unclear risk	Judgement Comment: Result could be reported in more details
Other bias	High risk	Judgement Comment: Crossover study without washout period and study using both legs even if this is not a proper way to do it.

Mariani 2013

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention ● *Age*: N/A ● *Number of Females*: 13 ● *Mean weight*: N/A ● *Mean BMI*: N/A ● *Main reason for chronic edema*: CVI

	● *mobile/immobile*: N/A ● *Number of males*: 13 control ● *Age*: N/A ● *Number of Females*: 20 ● *Mean weight*: N/A ● *Mean BMI*: N/A ● *Main reason for chronic edema*: CVI ● *mobile/immobile*: N/A ● *Number of males*: 10 Overall ● *Age*: 63,9 ● *Number of Females*: 33 ● *Mean weight*: ● *Mean BMI*: ● *Main reason for chronic edema*: ● *mobile/immobile*: ● *Number of males*: **Included criteria:** male or female, 18-90 yearsunilateral or bilateral CVIchronic stable pitting edemano effective compression **Excluded criteria:** Most important:<18 or > 90effective compression befor studyDMrenal and liver insuffhypoalbuminaemiaacute DVT or SVTactive ulcerationlymphedemalipedemamalignancy **Pretreatment:**
Interventions	**Intervention Characteristics** Intervention ● *time interval*: 1 week ● *description of treatment with compression stockings*: below knee compression stockings control ● *time interval*: 1 week ● *description of treatment with compression stockings*: Placebo stocking. Pressure 3-6 mmHg
Outcomes	*Ødem (edema) End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome ● **Direction**: Higher is better *Tilbagevendende sår (recurrent ulcer) End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome *Tilbagevendende sår (recurrent ulcer) Follow up ≤ 12 mdr.* ● **Outcome type**: DichotomousOutcome *Tilbagevendende sår (recurrent ulcer) Follow up 12 mdr.-24 mdr.* ● **Outcome type**: DichotomousOutcome *Smerter (bivirkning) (pain) End of treatment, max 12 mdr.* ● **Outcome type**: ContinuousOutcome *Hudforandringer (skin changes) End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome *Livskvalitet (quality of life) End of treatment, max 12 mdr.* ● **Outcome type**: ContinuousOutcome *Roseninfektion (Erysipelas, Cellulitis) End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome *Roseninfektion (Erysipelas, cellulitis)Follow up ≥ 12 mdr.* ● **Outcome type**: DichotomousOutcome *Drop out End of treatment, max 12 mdr.* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** N/A **Country:** Italy **Setting:** Vascular surgery unit **Comments:** **Authors name:** F Mariani **Institution:** Vascular surgery, Siena, Italy **Email:** brtma@tin.it **Address:** The compression therapy study grpou, Collle di Val d´Elsa, Siena, Italy
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	described as "random", but technique not desribed
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	High risk	no blinding
Blinding of outcome assessment (detection bias)	Unclear risk	-
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Footnotes

References to studies

Included studies

Carvalho 2015

Carvalho, Carlos Alberto; Lopes Pinto, Renata; Guerreiro Godoy, Maria de Fatima; Pereira de Godoy, Jose Maria. Reduction of Pain and Edema of the Legs by Walking Wearing Elastic Stockings.. International Journal of Vascular Medicine 2015;2015(Journal Article):648074. [DOI: http://dx.doi.org/10.1155/2015/648074]

Mariani 2013

Mariani F.; Bucalossi M.; Mancini S.. Placebo controlled efficacy of class 2 elastic stockings (23-32 mmHg) in reduction of edema in CVI of the lower limbs. Acta Phlebologica 2013;14(1):39-44. [DOI:]

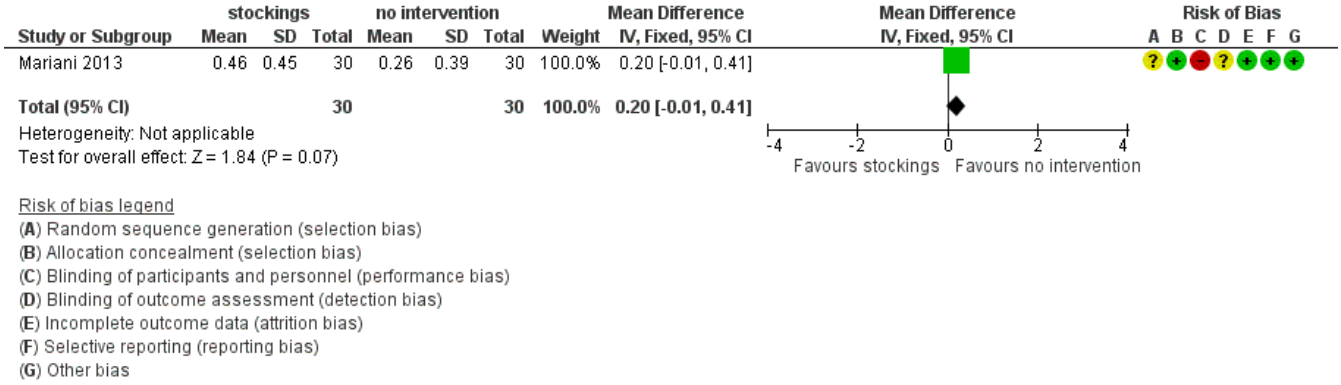
Data and analyses

1 Compression stockings vs no intervention

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Smerter (bivirkning) (pain) End of treatment, max 12 mdr.	1	60	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.01, 0.41]
1.2 Livskvalitet (quality of life) End of treatment, max 12 mdr.	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.3 Ødem (edema) End of treatment, max 12 mdr.	1	42	Mean Difference (IV, Fixed, 95% CI)	-64.28 [-90.04, -38.52]
1.3.2 Time (change value)	1	42	Mean Difference (IV, Fixed, 95% CI)	-64.28 [-90.04, -38.52]
1.4 Total ødemreduktion (total reduction of edema) End of treatment, max 12 mdr.	1	60	Risk Ratio (IV, Fixed, 95% CI)	8.00 [2.69, 23.75]
1.4.1 Time (final value)	1	60	Risk Ratio (IV, Fixed, 95% CI)	8.00 [2.69, 23.75]
1.5 Tilbagevendende sår (recurrent ulcer) End of treatment, max 12 mdr.	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.6 Tilbagevendende sår (recurrent ulcer) Follow up ≤ 12 mdr.	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.7 Tilbagevendende sår (recurrent ulcer) Follow up 12 mdr.-24 mdr.	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.8 Hudforandringer (skin changes) End of treatment, max 12 mdr.	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.9 Roseninfektion (Erysipelas, Cellulitis) End of treatment, max 12 mdr.	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.10 Roseninfektion (Erysipelas, cellulitis) Follow up ≥ 12 mdr.	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.11 Drop out End of treatment, max 12 mdr.	1	60	Risk Ratio (IV, Fixed, 95% CI)	9.00 [0.51, 160.17]

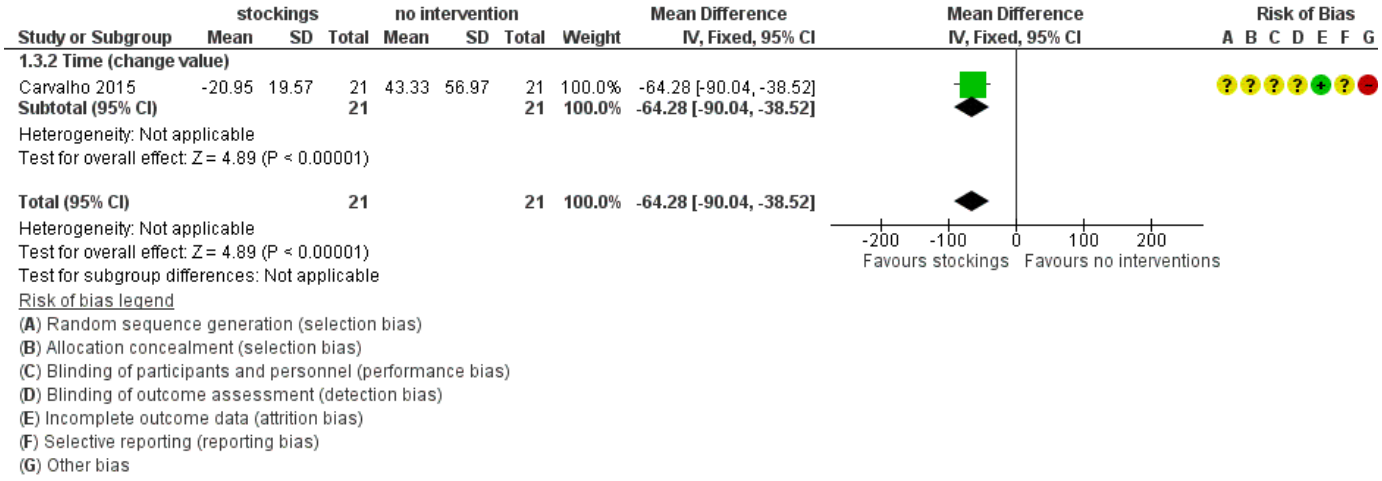
Figures

Figure 1 (Analysis 1.1)



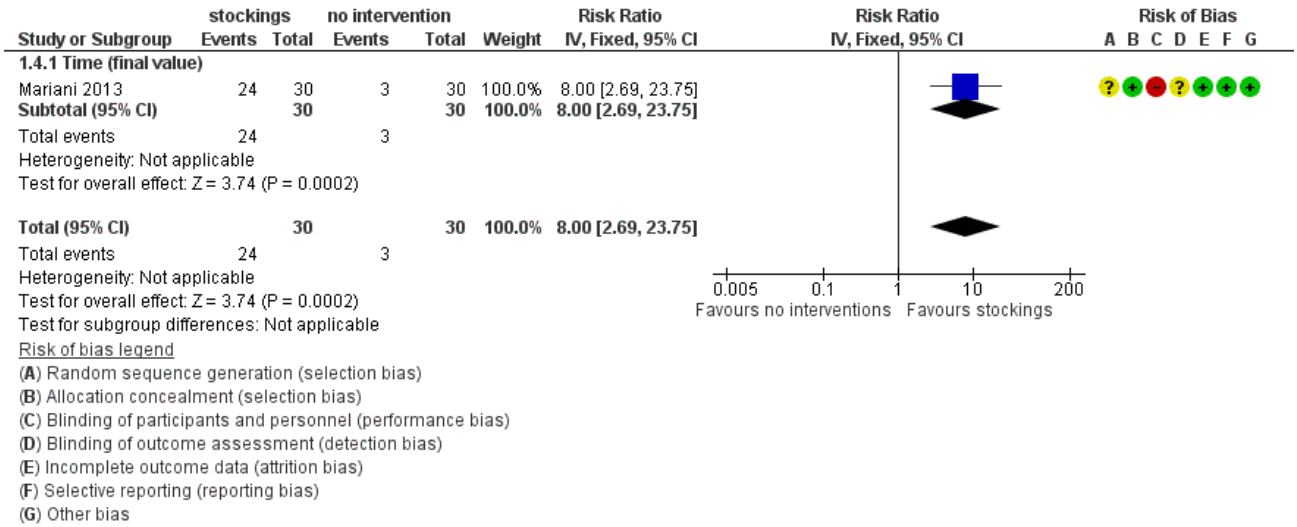
Forest plot of comparison: 1 Stockings vs no intervention, outcome: 1.1 Smerter (bivirkning) (pain) End of treatment, max 12 mdr..

Figure 2 (Analysis 1.3)



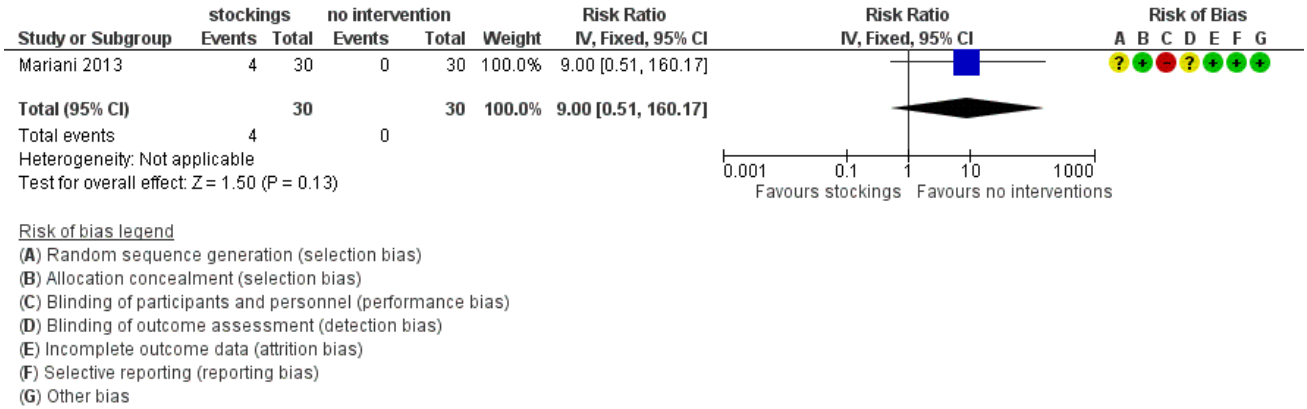
Forest plot of comparison: 1 Compression stockings vs no intervention, outcome: 1.3 Ødem (edema) End of treatment, max 12 mdr..

Figure 3 (Analysis 1.4)



Forest plot of comparison: 1 Stockings vs no intervention, outcome: 1.4 Total ødemreduktion (total reduction of edema) End of treatment, max 12 mdr..

Figure 4 (Analysis 1.11)



Forest plot of comparison: 1 Compression stockings vs no intervention, outcome: 1.11 Drop out End of treatment, max 12 mdr..