NKR52_Meniere_PICO 6_Meniett

Characteristics of studies

Characteristics of included studies

Gates 2004

Methods	
Participants	
Interventions	
Outcomes	
Notes	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
Allocation concealment (selection bias)	Low risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
Blinding of participants and personnel (performance bias)	Low risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
Blinding of outcome assessment (detection bias)	Low risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
Incomplete outcome data (attrition bias)	Unclear risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
Selective reporting (reporting bias)	High risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
Other bias	High risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015

Gurkov 2012

Methods	
Participants	
Interventions	
Outcomes	
Notes	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015

Risk of bias table

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Random sequence generation (selection bias)	Unclear risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
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Selective reporting (reporting bias)	Low risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
Other bias	Unclear risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015

Russo 2017

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group
Participants	**Baseline Characteristics** Intervention 1 • *Diagnosis*: • *Age*: 52 ± 1.6 • *Boys, %*: 40% Control • *Diagnosis*: • *Age*: 50 ± 1.9 • *Boys, %*: 47%

	Overall
	  ● *Diagnosis*:
	  ● *Age*:
	  ● *Boys, %*:
	
	Included criteria: All patients were adults over 18 years old age, affected by a stage 2, or greater, unilateral definite Menière's disease, according to the AAO-NHS criteria 2. They were included if they experienced at least two episodes of rotatory vertigo in the preceding two months (vertigo lasting at least 20 minutes, with a free interval of 12 hours), with or without associated tinnitus, and/or a sensation of fullness in the ear. Moreover, the impact of vertigo on the patient's daily life had to be at level 3 at least on the functionality level according to AAO- HNS criteria.
	Excluded criteria: Patients having undergone surgical treatment or chemical labyrinthectomy for Menière's disease were excluded
	Pretreatment: No other apparent differences at baseline

Interventions	**Intervention Characteristics**
	Intervention 1
	  ● *Description*: Ventilation tube + Meniett device
	  ● *Length of treatment*: 6 weeks
	  ● *Longest follow-up after end of treatment*: 6 weeks
	
	Control
	  ● *Description*: Ventilation tube + Placebo device
	  ● *Length of treatment*: 6 weeks
	  ● *Longest follow-up after end of treatment*: 6 weeks

Outcomes	*Anfaldshyppighed, mean SEM*
	  ● **Outcome type**: ContinuousOutcome
	
	Activities of daily life, mean SEM
	  ● **Outcome type**: ContinuousOutcome
	
	Number of vertigo attackts, n (improvement in 2nd phase, 2nd period)
	  ● **Outcome type**: DichotomousOutcome

Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was performed by blocks of four. Each center received a block of four devices (2 Meniett® and 2 Placebo). If necessary, according to the rate of inclusion in a given center, more blocks of four devices were attributed to the center."
Allocation concealment (selection bias)	Low risk	Quote: "The boxes were randomly numerated and the physician did not know their content, and had to distribute them to the patients. The placebo was identical in all aspects to the active device, but did not generate pressure pulses."
Blinding of participants and personnel (performance bias)	Low risk	Quote: "The boxes were randomly numerated and the physician did not know their content, and had to distribute them to the patients. The placebo was identical in all aspects to the active device, but did not generate pressure pulses. The" Judgement Comment: Mentioned as double-blinded
Blinding of outcome assessment (detection bias)	Unclear risk	Judgement Comment: Nothing mentioned
Incomplete outcome data (attrition bias)	Low risk	Judgement Comment: No dropouts
Selective reporting (reporting bias)	Low risk	Judgement Comment: No apparent sources of bias
Other bias	Low risk	Judgement Comment: No apparent sources of bias

Thomsen 2005

Methods	
Participants	
Interventions	
Outcomes	
Notes	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
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Blinding of outcome assessment (detection bias)	Low risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015
Incomplete outcome data (attrition bias)	Unclear risk	For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015

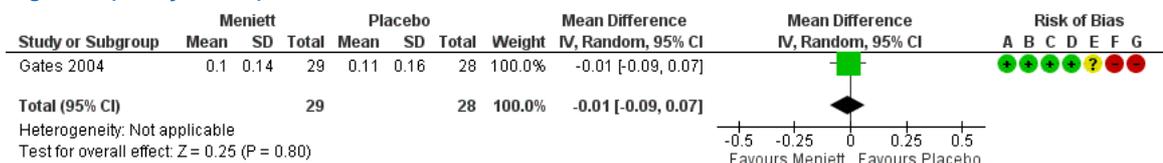| Selective reporting (reporting bias) | High risk | For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015 |
| Other bias | Unclear risk | For more information see: Van Sonsbeek et al "positive pressure therapy for Meniere" cochrane library 2015 |

Footnotes

Summary of findings tables

Data and analyses

2 Meniere apparatus vs Placebo apparatus

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Anfaldshyppighed. (Proportion of days with definitive vertigo) 4 mdr efter start af behandling	1	57	Mean Difference (IV, Random, 95% CI)	-0.01 [-0.09, 0.07]
2.2 Anfaldshyppighed. (Change in no. of days with definitive vertigo) 4 mdr efter start af behandlingen.	1	68	Mean Difference (IV, Fixed, 95% CI)	2.00 [-0.35, 4.35]
2.3 Anfaldshyppighed (Vertigo frequency) 2 mdr efter start af behandling	1	40	Mean Difference (IV, Fixed, 95% CI)	-2.10 [-5.25, 1.05]
2.4 Anfaldshyppighed (mean no. vertigo episoder, <20min) 6 uger efter start af behandling	1	77	Mean Difference (IV, Fixed, 95% CI)	0.15 [-0.02, 0.32]
2.5 Antal tilfælde af vertigo (improvement in number attacks lasting >20min) 6 uger efter start af behandling	1	77	Risk Ratio (IV, Fixed, 95% CI)	1.19 [0.82, 1.71]
2.6 Sværhedsgraden af anfaldet (vertigo score) 4 mdr efter start af behandling	1	68	Mean Difference (IV, Fixed, 95% CI)	5.31 [-2.40, 13.02]
2.9 Activities of daily life. 2-6 mdr efter start af behandling	3	185	Std. Mean Difference (IV, Random, 95% CI)	-0.38 [-0.87, 0.12]

Figures

Figure 1 (Analysis 2.1)

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: 2 Meniere apparatus vs Placebo apparatus, outcome: 2.1 Anfaldshyppighed. (Proportion of days with definitive vertigo) 4 mdr efter start af behandling.

Figure 2 (Analysis 2.2)
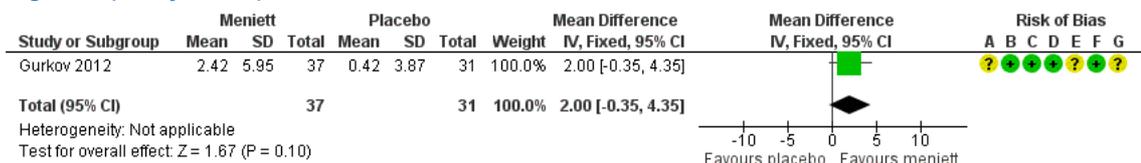

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting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

Forest plot of comparison: 2 Meniere apparatus vs Placebo apparatus, outcome: 2.2 Anfaldshyppighed. (Change in no. of days with definitive vertigo) 4 mdr efter start af behandlingen..

Figure 3 (Analysis 2.3)

Study or Subgroup	Meniett Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Thomsen 2005	1.9	4.1	20	4	5.9	20	100.0%	-2.10 [-5.25, 1.05]
Total (95% CI)			**20**			**20**	**100.0%**	**-2.10 [-5.25, 1.05]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.31 (P = 0.19)
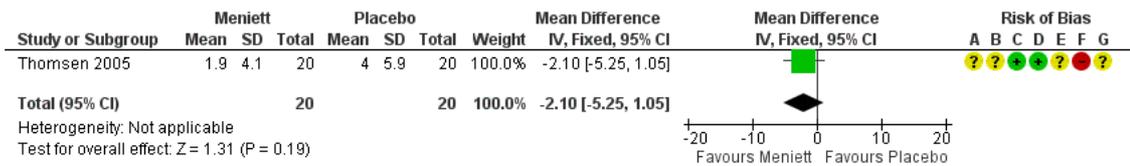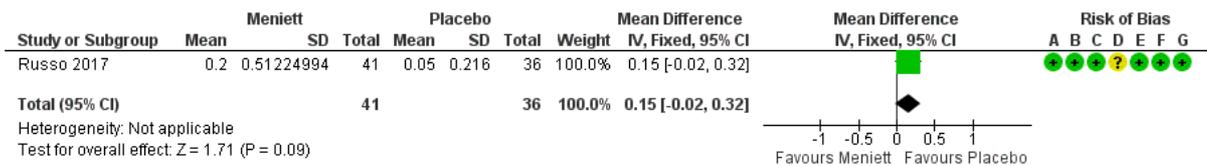

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting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

Forest plot of comparison: 2 Meniere apparatus vs Placebo apparatus, outcome: 2.3 Anfaldshyppighed (Vertigo frequency) 2 mdr efter start af behandling.
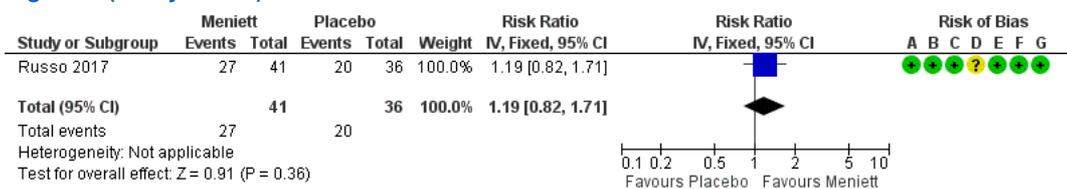
Figure 4 (Analysis 2.4)

Study or Subgroup	Meniett Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Russo 2017	0.2	0.51224994	41	0.05	0.216	36	100.0%	0.15 [-0.02, 0.32]
Total (95% CI)			**41**			**36**	**100.0%**	**0.15 [-0.02, 0.32]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.71 (P = 0.09)

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: 2 Meniere apparatus vs Placebo apparatus, outcome: 2.4 Anfaldshyppighed (mean no. vertigo episoder, <20min) 6 uger efter start af behandling.
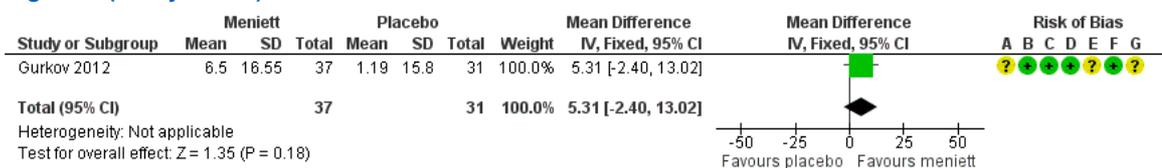
Figure 5 (Analysis 2.5)

Study or Subgroup	Meniett Events	Total	Placebo Events	Total	Weight	Risk Ratio IV, Fixed, 95% CI
Russo 2017	27	41	20	36	100.0%	1.19 [0.82, 1.71]
Total (95% CI)		**41**		**36**	**100.0%**	**1.19 [0.82, 1.71]**
Total events	27		20			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.91 (P = 0.36)

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: 2 Meniere apparatus vs Placebo apparatus, outcome: 2.5 Antal tilfælde af vertigo (improvement in number attacks lasting >20min) 6 uger efter start af behandling.
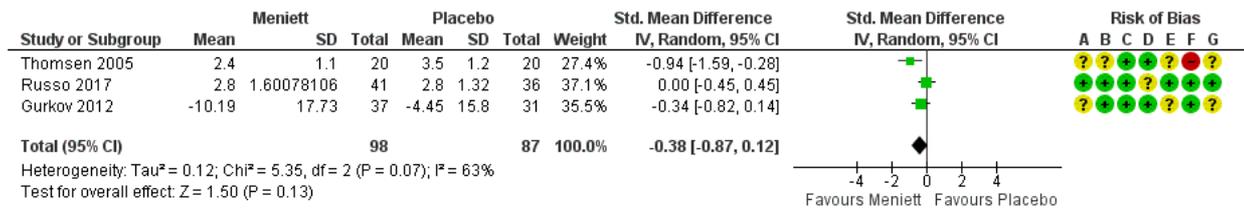
Figure 6 (Analysis 2.6)

Study or Subgroup	Meniett Mean	SD	Total	Placebo Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Gurkov 2012	6.5	16.55	37	1.19	15.8	31	100.0%	5.31 [-2.40, 13.02]
Total (95% CI)			**37**			**31**	**100.0%**	**5.31 [-2.40, 13.02]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.35 (P = 0.18)

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: 2 Meniere apparatus vs Placebo apparatus, outcome: 2.6 Sværhedsgraden af anfaldet (vertigo score) 4 mdr efter start af behandling.

Figure 8 (Analysis 2.9)

Study or Subgroup	Meniett Mean	SD	Total	Placebo Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Thomsen 2005	2.4	1.1	20	3.5	1.2	20	27.4%	-0.94 [-1.59, -0.28]
Russo 2017	2.8	1.60078106	41	2.8	1.32	36	37.1%	0.00 [-0.45, 0.45]
Gurkov 2012	-10.19	17.73	37	-4.45	15.8	31	35.5%	-0.34 [-0.82, 0.14]
Total (95% CI)			98			87	100.0%	-0.38 [-0.87, 0.12]

Heterogeneity: Tau² = 0.12; Chi² = 5.35, df = 2 (P = 0.07); I² = 63%
Test for overall effect: Z = 1.50 (P = 0.13)

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: 2 Meniere apparatus vs Placebo apparatus, outcome: 2.9 Activities of daily life. 2-6 mdr efter start af behandling.