# NKR52\_Meniere\_PICO9\_Kirurgi

# **Characteristics of studies**

## **Characteristics of included studies**

# Bretlau 1989

| Methods        |   |
|----------------|---|
| Participants   |   |
| Interventions  |   |
| Outcomes       |   |
| Identification |   |
| Notes          | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |

## Risk of bias table

| Bias  | Authors' judgement | Support for judgement   |
|---|--------------------|---|
| Random sequence generation (selection bias)               | Unclear risk       | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Allocation concealment (selection bias)                   | Unclear risk       | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Blinding of participants and personnel (performance bias) | Low risk           | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Blinding of outcome assessment (detection bias)           | Low risk           | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Incomplete outcome data (attrition bias)                  | High risk          | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Selective reporting (reporting bias)                      | Low risk           | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Other bias  | Low risk           | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |

## Thomsen 1981

| Methods        | Study design: Randomized controlled trial   |
|----------------|---|
|                | Study grouping: Parallel group  |
| Participants   | Baseline Characteristics Intervention 1  • Age: 49.9  • Boys %: 60  |
|                | Control  • Age: 53.9  • Boys %: 60  |
|                | Included criteria: - Presence of typical attacks of fluctuating hearing loss, tinnitus and vertigo, often accompanied by nausea, vomiting and pressure in the ear with at least attack every two weeks, - A history of at least six months of disease, but no longer then five years Normal renal, cardiac and thyroid functionNo allergies The patients has to be considered psychologically normal.  Excluded criteria: Tumor or other pathologic conditions in the cerebellopontine angle. |
| Interventions  | Intervention Characteristics Intervention 1  • Description: Regular endolymphatic sac shunt operation with insertion of Silastic into the sac, draining out into the mastoid cavity.  • Longest follow-up after end of treatment: 12 months   |
|                | Control  • Description: Regular mastoidectomy  • Longest follow-up after end of treatment: 12 months  |
| Outcomes       | Evaluation of operative good effect from patients (1year and 9 year FU)   |
| Identification | Country: Denmark Setting: 2 University hospitals Authors name: Jens Thomsen Institution: Ear, Nose and Throat Department, Rigshospitalet, Copenhagen Address: Ear, Nose and Throat Department, Gentofte Hospital, Hellerup, DK-2900, Denmark  |
| Notes          |   |

Review Manager 5.3

## Risk of bias table

| Bias  | Authors' judgement | Support for judgement                                       |
|---|--------------------|---|
| Random sequence generation (selection bias)               | Unclear risk       | Nothing mentioned   |
| Allocation concealment (selection bias)                   | Unclear risk       | Nothing mentioned   |
| Blinding of participants and personnel (performance bias) | Unclear risk       | Nothing mentioned   |
| Blinding of outcome assessment (detection bias)           | Low risk           | Judgement Comment: Patients assessed at different hospitals |
| Incomplete outcome data (attrition bias)                  | Low risk           | No apparent sources of bias                                 |
| Selective reporting (reporting bias)                      | Low risk           | No apparent sources of bias                                 |
| Other bias  | Low risk           | No apparent sources of bias                                 |

## Thomsen 1998

| Methods        |   |
|----------------|---|
| Participants   |   |
| Interventions  |   |
| Outcomes       |   |
| Identification |   |
| Notes          | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |

## Risk of bias table

| Bias  | Authors' judgement | Support for judgement   |
|---|--------------------|---|
| Random sequence generation (selection bias)               | Unclear risk       | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Allocation concealment (selection bias)                   | Low risk           | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Blinding of participants and personnel (performance bias) | High risk          | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Blinding of outcome assessment (detection bias)           | High risk          | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Incomplete outcome data (attrition bias)                  | Low risk           | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Selective reporting (reporting bias)                      | High risk          | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |
| Other bias  | Low risk           | For more information see: Pullens et al "Surgery for Meniere" Cochrane library 2013 |

Footnotes

## **Characteristics of excluded studies**

## Saliba 2015

Footnotes

# **Characteristics of studies awaiting classification**

Footnotes

# **Characteristics of ongoing studies**

Footnotes

# Summary of findings tables Additional tables References to studies

#### **Included studies**

## Bretlau 1989

[Empty]

#### Thomsen 1981

Thomsen, J.; Bretlau, P.; Tos, M.; Johnsen, N. J.. Placebo effect in surgery for Meniere's disease. A double-blind, placebo-controlled study on endolymphatic sac shunt surgery. Archives of otolaryngology (Chicago, Ill.: 1960) 1981;107(5):271-277. [DOI: ]

#### Thomsen 1998

[Empty]

## **Excluded studies**

#### Saliba 2015

\* Endolymphatic duct blockage: A randomized controlled trial of a novel surgical technique for Meniere's disease treatmentOtolaryngology - Head and Neck Surgery (United States) 2015;152(1):122-129.

## Studies awaiting classification

**Ongoing studies** 

#### Other references

#### **Additional references**

## Other published versions of this review

Classification pending references

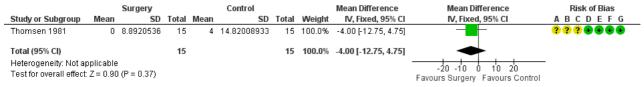
# **Data and analyses**

## 1 Surgery vs Control

| Outcome or Subgroup  | Studies | Participants | Statistical Method                  | Effect Estimate      |
|--|---------|--------------|-------------------------------------|----------------------|
| 1.3 Vertigo score. 1 year follow-up                                | 1       | 30           | Mean Difference (IV, Fixed, 95% CI) | -4.00 [-12.75, 4.75] |
| 1.4 Good operative effect, estimated by patient.  1 year follow-up | 1       | 30           | Risk Ratio (IV, Fixed, 95% CI)      | 1.10 [0.69, 1.76]    |
| 1.5 Good operative effect, estimated by patient. 9 year follow-up  | 1       | 23           | Risk Ratio (IV, Fixed, 95% CI)      | 1.25 [0.68, 2.27]    |

# **Figures**

## Figure 1 (Analysis 1.3)

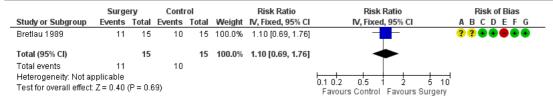


## Risk of bias legend

- (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 Surgery vs Control, outcome: 1.3 Vertigo score. 1 year follow-up.

## Figure 2 (Analysis 1.4)

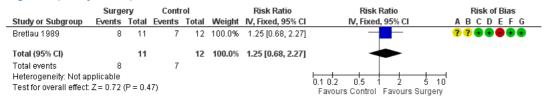


#### Risk of bias legend

- (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 Surgery vs Control, outcome: 1.4 Good operative effect, estimated by patient. 1 year follow-up.

## Figure 3 (Analysis 1.5)



#### 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 Surgery vs Control, outcome: 1.5 Good operative effect, estimated by patient. 9 year follow-up.