

# Management of bartholin gland cyst and abscess: marsupialization or word catheter.

Published: 19-05-2010

Last updated: 02-05-2024

Marsupialization and placement of a word catheter for the management of the cyst or abscess of the bartholin gland will be studied. Medical effectiveness in terms of recurrence of the cyst or abscess after 1 year follow up will be evaluated. Patient...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Female reproductive tract infections and inflammations
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON34700

### Source

ToetsingOnline

### Brief title

WoMan

### Condition

- Female reproductive tract infections and inflammations

### Synonym

bartholinitis, swelling of the labia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Bartholin gland, cyst or abscess, marsupialization, word catheter

## Outcome measures

### Primary outcome

Recurrence rate of cysts or abscess of the bartholin gland 1 year after treatment.

### Secondary outcome

Which treatment option (marsupialization or word catheter) is preferred by the patient?

Which treatment option (marsupialization or word catheter) gives the least pain during and after the procedure?

## Study description

### Background summary

Cysts or abscesses of the bartholin gland are common problems in women of reproductive age. They can cause pain and limitation of activity. Various treatment options are used to resolve the problem. The objective of these procedures is to drain the cyst or abscess and create a permanent outflow tract to prevent the recurrence of the cyst or abscess. Marsupialization and placement of a word catheter are commonly used methods in the Netherlands. It is unclear which treatment option gives the least relapses and the most patient satisfaction. The present proposal will study the effects of these treatment options. The proposal will consider recurrence, post operative pain and patient preferences.

### Study objective

Marsupialization and placement of a word catheter for the management of the cyst or abscess of the bartholin gland will be studied. Medical effectiveness in terms of recurrence of the cyst or abscess after 1 year follow up will be evaluated. Patient satisfaction and postoperative pain will also be evaluated. We will answer the following questions:

1. Which treatment option (Marsupialization or Word catheter) gives the least recurrences of the cyst or abscess of the Bartholin gland after 1 year follow up?
2. Which treatment option (Marsupialization or Word catheter) is preferred by the patients?
3. Which option (Marsupialization or Word catheter) gives the least postoperative pain?

## **Study design**

Multicenter randomized controlled trial.

## **Intervention**

Patients will be randomized for treatment by marsupialization or by placement of a word catheter.

## **Study burden and risks**

Depending on the complaints caused by the cyst or abscess of the Bartholin gland patients will undergo treatment as soon as possible. Both treatment options are often practiced in all hospitals in the Netherlands. During the follow up of one year patients will receive a questionnaire by e-mail to assess their pain 1 day, 1 week and 3 months after the treatment. After one year all patients receive a questionnaire to assess patient preferences.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients visiting the outpatient clinic with a symptomatic cyst or abscess of the bartholin gland, which requires surgical treatment at the moment.

### Exclusion criteria

- patients who don't give their informed consent
- patients with contraindications for one of the procedures at the time of randomization ( for example: patients with contraindication for general anaesthesia)
- patients who do not master dutch or english language
- Patients who are younger than 18 years of age and mentally competent

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-02-2010  
Enrollment: 160  
Type: Anticipated

## Ethics review

Approved WMO  
Application type: First submission  
Review commission: METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL30532.018.10