

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

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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...

Ethical review	Approved WMO
Status	Pending
Health condition type	Female reproductive tract infections and inflammations
Study type	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

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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