

# Limberg-flap versus primary closure in the midline after primary excision of a pilonidal sinus

Published: 16-12-2014

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n.v.t.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Skin and subcutaneous tissue disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON44556

### Source

ToetsingOnline

### Brief title

Limberg-trial

### Condition

- Skin and subcutaneous tissue disorders
- Skin and subcutaneous tissue therapeutic procedures

### Synonym

pilonidal cyst, pilonidal sinus

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente

**Source(s) of monetary or material Support:** er gebeurt niets dat extra geld kost

## Intervention

**Keyword:** limberg flap, pilonidal sinus, primary closure in midline

## Outcome measures

### Primary outcome

n.v.t.

### Secondary outcome

n.v.t.

## Study description

### Background summary

n.v.t.

### Study objective

n.v.t.

### Study design

n.v.t.

### Intervention

n.v.t.

### Study burden and risks

n.v.t.

## Contacts

### Public

Medisch Spectrum Twente

Koningsplein 1  
Enschede 7512 KZ  
NL  
**Scientific**  
Medisch Spectrum Twente

Koningsplein 1  
Enschede 7512 KZ  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

primary or recurrent pilonidal sinus  
width of fistulacomplex between 1 and 3 centimeter  
signed informed consent  
age:  $\geq$  18 years  
mentally competent

### **Exclusion criteria**

patients with an actual abscess  
not able to follow-up  
patients in which woundhealing problems are to be expected (Diabetes type II,  
immunesupression, chemotherapy, HIV/AIDS)  
not mentally competent  
dementia

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-05-2015

Enrollment: 74

Type: Actual

## Ethics review

Approved WMO

Date: 16-12-2014

Application type: First submission

Review commission: METC Twente (Enschede)

Approved WMO

Date: 28-07-2015

Application type: Amendment

Review commission: METC Twente (Enschede)

Approved WMO

Date: 07-07-2016

Application type: Amendment

Review commission: METC Twente (Enschede)

## Study registrations

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

No registrations found.

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

ID: 22628

Source: NTR

Title:

## In other registers

Register	ID
Other	21001
CCMO	NL49989.044.14
OMON	NL-OMON22628