

# Topical zinc oxide for open pilonidal sinus wounds: a randomised, double-blind, placebo-controlled multicentre trial

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>20/09/2004   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>29/09/2004 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>25/09/2009       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Magnus Ågren

### Contact details

Department of Surgery K  
Bispebjerg Hospital  
University of Copenhagen  
Bispebjerg Bakke 23  
Copenhagen  
Denmark  
DK-2400  
+45 35316493  
[magnus.agren@get2net.dk](mailto:magnus.agren@get2net.dk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

ZÅRSTUDIET

## Study objectives

Locally applied zinc oxide (ZnO) may be beneficial for various types of human wounds. This randomised, double-blind, placebo-controlled multicentre trial compared the effect of topical ZnO with placebo under moist conditions on the healing of excisional wounds following surgical removal of the pilonidal sinus.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

No ethics information required at time of registration.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Pilonidal excisional wound

## Interventions

Zinc oxide and polyvinylpyrrolidone versus polyvinylpyrrolidone alone

## Intervention Type

Drug

## Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

Topical zinc oxide

**Primary outcome measure**

Time to wound closure in days, defined by complete coverage of the wound with visible epithelium.

**Secondary outcome measures**

Secondary outcomes were:

1. Postoperative antibiotic treatment
2. Re-operations
3. Pain intensity
4. Adverse events

Tertiary outcomes were:

1. Serum-zinc levels
2. Sick leave

**Overall study start date**

01/02/2002

**Completion date**

01/05/2004

## **Eligibility**

**Key inclusion criteria**

Patients, 18 years or older, with a first-episode of pilonidal abscess requiring surgery are included after giving their written informed consent.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

75

**Key exclusion criteria**

Previous pilonidal surgery, hypersensitivity to zinc, dementia, insufficiency in Danish, pregnancy or lactation.

**Date of first enrolment**

01/02/2002

**Date of final enrolment**

01/05/2004

## **Locations**

**Countries of recruitment**

Denmark

**Study participating centre**

Department of Surgery K

Copenhagen

Denmark

DK-2400

## **Sponsor information**

**Organisation**

Bispebjerg Hospital (Denmark)

**Sponsor details**

Department of Surgery K

Bispebjerg Hospital

University of Copenhagen

Bispebjerg Bakke 23

Copenhagen

Denmark

DK-2400

+45 35316493

magnus.agren@get2net.dk

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/00td68a17>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Apotekerfonden 1991, Abigo Medical AB

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/09/2006   |            | Yes            | No              |