

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

Submission date 20/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/09/2009	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Apotekerfonden 1991, Abigo Medical AB

Results and Publications

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?
Results article	results	01/09/2006		Yes	No