ISRCTN35311675 https://doi.org/10.1186/ISRCTN35311675

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2004	**Overall study status** Completed	
Last Edited 25/09/2009	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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?
Results article	results	01/09/2006		Yes	No