ISRCTN44896217 https://doi.org/10.1186/ISRCTN44896217

A randomised trial of Bascom's procedure versus cleft closure for the management of primary pilonidal sinus disease

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 05/05/2010	**Condition category** Ear, Nose and Throat	

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
N0213108766

Study information

Scientific Title

Study objectives
To test the hypothesis that Bascom's procedure for pilonidal sinus is as successful as cleft closure with respect to postoperative complications, time to complete healing and long-term recurrence rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ear, Nose and Throat: Pilonidal sinus disease

Interventions
Randomised to treatment by Bascom's procedure or cleft closure.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/09/2001

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Age over 16
2. Chronic pilonidal sinus disease that consultant considers to be suitable for Bascom's procedure
3. Patient willing to attend long-term follow-up

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Added 05/05/10: 55

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2001

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Directorate of Surgery
Chichester
United Kingdom
PO19 4SE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Royal West Sussex Trust (UK)

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	01/02/2009	Yes	No