

Efficacy of saline douching following endoscopic sinus surgery (ESS)

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/05/2009	Condition category Surgery	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0188124835

Study information

Scientific Title

Study objectives

To evaluate the effect of postoperative saline douching following endoscopic sinus surgery

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**

Surgery: Endoscopic sinus surgery (ESS)

Interventions

Randomised Controlled Study

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Reduction of complications following operation and improvement in sinonasal symptoms at 3 weeks and then at 3 months.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2003

Completion date

01/02/2006

Eligibility

Key inclusion criteria

1. Aged 18 or over
2. Diagnosis of acute or chronic rhinosinusitis or nasal polyposis
3. Patient listed for bilateral endoscopic sinus surgery

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

40 patients

Key exclusion criteria

Other nasal surgery performed concomitantly, diagnosed with inflammatory or neoplastic nasal pathology, diagnosed with systemic conditions affecting the nose, gross difference in contralateral sinonasal disease as assessed radiologically and operatively, unilateral trimming of middle turbinate during ESS, patients listed for revision surgery, neoplasms-untreated or under active or recent tx with chemotherapy or radiotherapy, major psychiatric illness active or untreated with previous hospitalisation.

Date of first enrolment

01/04/2003

Date of final enrolment

01/02/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Otolaryngology

Chorley

United Kingdom

PR7 1PP

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Lancashire Teaching Hospitals NHS 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	01/10/2008		Yes	No