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Efficacy of saline douching following endoscopic sinus surgery (ESS)

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/05/2009	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
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
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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