Efficacy of saline douching following endoscopic sinus surgery (ESS)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2005		☐ 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

Contact name

Mr S Freeman

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre Otolaryngology

Chorley United Kingdom PR7 1PP

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Lancashire Teaching Hospitals NHS Trust (UK)

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	01/10/2008		Yes	No