ISRCTN64097182 https://doi.org/10.1186/ISRCTN64097182

Middle turbinate medialisation using a transfixion suture following functional endoscopic sinus surgery: how effective is it in maintaining patency of the middle meatus?

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
24/04/2012

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr T H Malik

Contact details
East Lancashire Hospitals NHS Trust
The Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0300148808

Study information

Scientific Title

Study objectives
Does medialising the middle turbinate with a single transfixion suture after functional endoscopic sinus surgery FESS improve the outcome of 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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Nose

Interventions
1. Medialisation of Middle Turbinate with transfixion suture performed
2. Suture not performed

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

Pain, nasal obstruction, sense of smell, ante/post rhinorrhoea.

Secondary outcome measures
Size of access of middle meatus, presence/absence of adhesions.

Overall study start date
01/10/2003

Completion date
01/10/2004

Eligibility

Key inclusion criteria
Patients undergoing anterior/ posterior ethmiodal FESS +/- Septoplasty.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Patients in whom middle turbinate has been trimmed, previous septal or middle turbinate surgery.

Date of first enrolment
01/10/2003

Date of final enrolment
01/10/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East Lancashire Hospitals NHS Trust
Blackburn

United Kingdom
BB2 3HH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, 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
East Lancashire 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	01/06/2005		Yes	No