

The effect of post-operative nasal packing on mucociliary activity

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 31/03/2020	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0025107235

Study information

Scientific Title

The effect of post-operative nasal packing on mucociliary activity

Study objectives

We expect that nasal packs disrupt the nasal mucosal membrane for up to 3 months causing increased morbidity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Prospective randomised controlled pilot study

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: Post-operative nasal packing

Interventions

Patients will be randomised to receive either Merocel, Vasolene gauze or no packs. The effect on the mucociliary transport will be assessed by performing a saccharin clearance test pre-operatively, after removal of packs prior to discharge and at subsequent clinic follow-up. It is envisaged that the packs will significantly alter the mucociliary transport time, leading to increased post-operative morbidity. This will lead to an alteration in departmental policy and fewer patients will be packed as a result. Data analysis of the results to assess the mucociliary transport rates will be done.

Intervention Type

Procedure/Surgery

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

01/06/2003

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

40 ENT patients

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2001

Date of final enrolment

01/06/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospital Aintree

Liverpool

United Kingdom

L9 7AL

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**

Hospital/treatment centre

Funder Name

Aintree 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