ISRCTN27163398 https://doi.org/10.1186/ISRCTN27163398

The effect of post-operative nasal packing on mucociliary activity

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/03/2020	Ear, Nose and Throat	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Tristram Hugh John Lesser

Contact details
Otolaryngology
University Hospital Aintree
Longmoor Lane
Liverpool
United Kingdom
L9 7AL

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