ISRCTN42522811 https://doi.org/10.1186/ISRCTN42522811

A prospective , double blind, randomised controlled trial evaluating the effects of mitomycin C on postoperative healing following endoscopic sinus surgery (ESS) to the frontonasal recess.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 10/07/2008	**Condition category** 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
N0256159712

Study information

Scientific Title

Study objectives
The study aims to evaluate the effects of mitomycin C on wound healing, its effects in the prevention of the formation of adhesions as well as preventing restenosis.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Endoscopic sinus surgery (ESS)

Interventions
Patients undergoing ESS to the frontonasal recess for chronic rhinosinusitis are randomly allocated to receive either MMC or placebo solution applied to the frontonasal recess.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
mitomycin C

Primary outcome measure
1. Patency of the frontonasal recess.
2. Study of the formation of adhesions and rate of restenosis post operatively.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2005

Completion date
01/01/2006

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
20

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of ENT, RNTNE
London
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Royal Free Hampstead NHS Trust (UK)

Funder Name
Professorial Unit RNTNE

Funder Name
NHS R&D Support Funding

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 of pilot study	01/11/2006		Yes	No