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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
1. Patency of the frontonasal recess.
2. Study of the formation of adhesions and rate of restenosis post operatively.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/01/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Department of ENT, RNTNE
London
United Kingdom
WC1X 8DA

Sponsor information

Organisation
Department of Health

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

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