

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2008	Condition category Surgery	<input type="checkbox"/> Individual participant data

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