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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Valerie J Lund

Contact details

Department of ENT, RNTNE
Royal Free Hampstead NHS Trust
330 Grays Inn Road
King's Cross
London
United Kingdom
WC1X 8DA
+44 (0)20 7915 1300
v.lund@ucl.ac.uk

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 WC1X 8DA

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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 |