

Grafts of autologous epithelial cells for non-healing mastoid cavities: a randomised clinical trial

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/06/2014	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
SPGS351

Study information

Scientific Title

Study objectives

To determine the effectiveness of autologous grafts of cultured buccal epithelial cells for non-healing mastoid cavities and to provide evidence that the trouble and costs of obtaining the cultured epithelial cells are necessary.

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

Ear, nose and throat diseases

Interventions

All patients to have biopsy taken and cells grown. Randomised to receive graft or no graft

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

31/03/1997

Completion date

31/03/2000

Eligibility

Key inclusion criteria

100 patients with mastoid cavities not healed 6 months after creation

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

31/03/1997

Date of final enrolment

31/03/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Blond McIndoe Centre

East Grinstead

United Kingdom

RH19 3DZ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
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.doh.gov.uk>

Funder(s)**Funder type**

Government

Funder Name

NHS Executive South East (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