

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/03/2000

Eligibility**Key inclusion criteria**

100 patients with mastoid cavities not healed 6 months after creation

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

31/03/1997

Date of final enrolment

31/03/2000

Locations

Countries of recruitment

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration