

Randomised controlled trial of reconstruction against secondary intention healing of defects of the medial canthus

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/09/2015	Condition category Surgery	<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

Protocol serial number
N0192080944

Study information

Scientific Title

Randomised controlled trial of reconstruction against secondary intention healing of defects of the medial canthus

Study objectives

How do the results of formal reconstruction of defects of the medial canthus compare against healing by secondary intention, following tumour excision?

01/09/2015: Trial was abandoned in 1999 due to an inability to recruit participants as all patients wanted to be in the intervention group.

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

Surgery: Reconstruction of medial canthus

Interventions

Randomised controlled trial.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Snellen visual acuity, diplopia, patency of lacrimal system, lid mal-positions, features of corneal exposure, photographs with four expressions, quality of life assessment.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/1999

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

60>, Caucasian, less than 1/3 of either upper or lower lid being involved, dimension of defect must measure less than 4x4 cm, the centre of the defect must be within 1.5 cm of the medial canthal tendon.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

17/02/1999

Date of final enrolment

31/12/1999

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Ophthalmology

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Nottingham University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration