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

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Stopped	
Last Edited 01/09/2015	**Condition category** Surgery	

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 abondoned 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

Study design
Randomised controlled trial

Primary study design
Interventional

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)
Snelen 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