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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/02/1999

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

Age group
Senior

Sex
Not Specified

Target number of participants
50

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

England

United Kingdom

Study participating centre
Department of Ophthalmology
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Nottingham University Hospitals NHS Trust (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