

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

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

**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)**

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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes