

# 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

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

### 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**

Snellen 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