

Lateral tarsal strip and everting sutures vs lateral tarsal strip and Jones procedure for involutional entropion: 2 year prospective randomized controlled trial

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/08/2012	Condition category Eye Diseases	<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

N0436186550

Study information

Scientific Title

Study objectives

This trial will compare two methods of surgically correcting age-related in-turning of the eyelid (involutional entropion) and address the following: which is the commonest malposition of the eyelid seen in our practice?

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Eye Diseases: Involutional entropion

Interventions

Questionnaire. Lateral tarsal strip and everting sutures compared to lateral tarsal strip and Jones procedure.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The functional (absence of symptoms) cosmetic (patient satisfaction with appearance) and anatomical (as assessed by surgeon) success of the procedure at final follow up visit.

Secondary outcome measures

Not provided at time of registration

Overall study start date

22/06/2006

Completion date

01/03/2009

Eligibility

Key inclusion criteria

1. Patients older than 60 years of age with primary involutional lower lid entropion
2. Patients suitable for local anaesthetic
3. Patients able to consent for the procedure

Participant type(s)

Patient

Age group

Senior

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

22/06/2006

Date of final enrolment

01/03/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Ophthalmology Department
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Leeds Teaching Hospitals NHS Trust

Funder Name

NHS R&D Support Funding

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