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Evaluation of Lacrimal Stent (mini monoka) for treatment of punctal stenosis: a prospective randomised comparative study

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/10/2017	**Condition category** Eye Diseases	[_] Individual participant data [_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0214126228

Study information

Scientific Title
Evaluation of Lacrimal Stent (mini monoka) for treatment of punctal stenosis: a prospective randomised comparative study

Study objectives
What is the use of lacrimal stent to relieve clinically significant Epiphora caused by punctal stenosis.

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
Eye Diseases: Epiphora

Interventions
Randomised comparative study of single snip procedure vs mini monoka (monocanalicular lacrimal stent)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Decrease in epiphora
1.1. subjectively using the questionnaire
1.2. objectively using fluoroscene dye disappearance test

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/05/2003

Completion date
30/09/2005

Eligibility

Key inclusion criteria
40 patients with punctal stenosis

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
30/05/2003

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

The Wolverhampton & Midland Counties Eye Infirmary
Wolverhampton Road
Wolverhampton
United Kingdom
WV3 9QR

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Royal Wolverhampton 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