Conservative vs surgical treatment of eyelid chalazia

Submission date	Recruitment status No longer recruiting	Prospectively regis	
29/09/2006		[] Protocol	
Registration date	Registration date Overall study status		
29/09/2006	Completed	[X] Results	
Last Edited 09/12/2010	Condition category Eye Diseases	[_] Individual participa	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0515174066

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Study information

Scientific Title

Study objectives

To identify which out of 3 options currently available for the management of eye lid cyst (chalazia) is the most effective one:

1. Surgical drainage of the cyst under local anaesthetic

2. Steroid injection into the cyst

3. No treatment

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

Health condition(s) or problem(s) studied Eye Diseases: Eyelid chalazia

Interventions Surgical drainage of the cyst under local anaesthetic vs steroid injection into the cyst vs no treatment

Intervention Type Other

Phase Not Specified

Primary outcome measure

Whether or not complete resolution of the chalazion is achieved at three weeks as a result of the treatment.

Secondary outcome measures

Degree of pain endured by patients, patients' level of satisfaction, any adverse events and the overall level of inconvenience.

Overall study start date

01/06/2005

Completion date

30/11/2007

Eligibility

Key inclusion criteria

- 1. Patients with a palpable chalazion or multiple chalaxia
- 2. Patients over 18 years old

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years

Sex Not Specified

Target number of participants 125

Key exclusion criteria

- 1. Patients with chalazia with atypical appearance
- 2. Patients allergic to any treatment
- 3. Patients under 18 years old
- 4. Patients without a palpable lid cyst or a concurrent eyelid infection

Date of first enrolment

01/06/2005

Date of final enrolment 30/11/2007

Locations

Countries of recruitment England United Kingdom

Study participating centre Department of Ophthalmology London United Kingdom NW10 7NS

Sponsor information

Organisation Record Provided by the NHSTCT Register - 2006 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 North West London Hospitals NHS Trust

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/11/2007		Yes	No