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Randomised controlled study of Lubrication with and without Bandage Contact Lens in primary treatment of Recurrent Corneal Erosion Syndrome

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
18/04/2012

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Maghizh Anandan

Contact details
Department of Ophthamology
Eye Block
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN
+44 0118 322 8150

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0199166145

Study information

Scientific Title

Study objectives
To compare lubrication alone as a treatment of recurrent corneal erosion against bandage contact lenses with lubrication on the rate of healing and subsequent recurrence of corneal ersion.

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: Recurrent corneal erosion syndrome

Interventions
Prospective, randomised controlled trial comparing lubrication alone as a treatment of recurrent corneal erosion against bandage contact lenses with lubrication on the rate of healing and subsequent recurrence of corneal erosions. Target 20 patients per group.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. Rate of healing and subsequent recurrence of corneal erosion
2. Symptom control
3. Incidence of adverse outcomes, particularly corneal infection

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/08/2005

Completion date
30/06/2008

Eligibility

Key inclusion criteria
All patients diagnosed with Recurrent Corneal Erosion Syndrome (RCES) seen in eye casualty on the basis of spontaneously recurring focal epithelial defect of epithelial defect diagnosed for the first time with characteristic symptoms of RCE

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
1. RCE with evidence of infection, as the management will differ due to infection
2. Patients with any other corneal pathology and those who have had surgical treatments for RCE in the past as they may affect the outcome of the study

Date of first enrolment
08/08/2005

Date of final enrolment
30/06/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Ophthamology
Reading
United Kingdom
RG1 5AN

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
Royal Berkshire and Battle 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2011		Yes	No