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Examination of the efficiency of ConHeal® sodium-hyaluronate containing eye drops in conjunctival and corneal epithelial injuries

Submission date 31/12/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 15/01/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 09/02/2023	**Condition category** Eye Diseases	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dry eye complaints are one of the top reasons for visiting ophthalmologists. Conjunctivochalasis is a common dry eye disorder, which can cause an unstable tear film and ocular discomfort. It is characterised by excess folds of the conjunctiva between the glove of the eye and the eyelid margin and it usually requires surgery, although a conservative therapy would be highly desirable.
The aim of the study is to assess whether a preservative-free, inorganic salt-free unit-dose artificial tear, called Conheal®, can improve vision-related quality of life, even in the case of severe conjunctivochalasis which would traditionally require surgery.

Who can participate?
Adult patients with severe conjunctivochalasis.

What does the study involve?
Patients are given Conheal® eye drops four times a day for 3 months.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Department of Ophthalmology, Semmelweis University, Hungary

When is the study starting and how long is it expected to run for?
From August 2012 to November 2013

Who is funding the study?
"Four our Eyesight" Foundation (Budapest, Hungary).

Who is the main contact?
Dr Huba Kiss

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
N/A

Study information

Scientific Title
Examination of the efficiency of ConHeal® sodium-hyaluronate containing eye drops in conjunctival and corneal epithelial injuries on patients with severe conjunctivochalasis measured by the LId-Parallel COnjunctival Folds (LIPCOF) degree, tear film breakup time, corneal lissamine green staining and Ocular Surface Disease Index (OSDI) questionnaire score

Study objectives
Four times a day application of the artificial tear drops, Conheal® (provided by Pannonpharma Ltd., Pécsvárad, Hungary), containing isotonic glycerol and 0.015% hyaluronic acid in purified water for 1 and 3 months decreases the LId-Parallel COnjunctival Folds (LIPCOF) degree characterizing severe conjunctivochalasis; increases tear film breakup time; reduces corneal lissamine green staining and decreases Ocular Surface Disease Index (OSDI) questionnaire score after 1 and 3 months of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hungarian Scientific and Research-Ethics Committee (http://www.ett.hu/tukeb.htm, tukeb@emmi.gov.hu), 07/12/2011, ref 21455-1/2011-EKU

Study design

Single-centre interventional trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Severe conjunctivochalasis, characterized by high LIPCOF degree, as both a reason and consequence of the dry eye disease.

Interventions
Patients receive the artificial tear drops, Conheal® (provided by Pannonpharma Ltd., Pécsvárad, Hungary), four times a day for 3 months. The drops contain isotonic glycerol and 0.015% hyaluronic acid in purified water

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Conheal® eye drops (provided by Pannonpharma Ltd., Pécsvárad, Hungary)

Primary outcome measure
Decrease in LId-Parallel COnjunctival Folds (LIPCOF) degree characterizing severe conjunctivochalasis after 1 and 3 months of treatment.

Secondary outcome measures
1. Increase in tear film breakup time, reduction of corneal lissamine green staining, decrease of Ocular Surface Disease Index (OSDI) questionnaire score after 1 and 3 months of treatment.

Overall study start date
27/08/2012

Completion date
04/11/2013

Eligibility

Key inclusion criteria
1. Female and male patients older than 18
2. Severe conjunctivochalasis (having LId-Parallel COnjunctival Folds, LIPCOF degree 2 or higher)
3. Lissamine green staining of minimum grade 1 or higher on the Oxford Scheme grade, indicating a more advanced dry eye disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Pregnancy or lactation
2. Pterygium
3. Prolonged treatment with eye drops with the exception of artificial tears
4. Active allergic keratoconjunctivitis
5. Current keratitis or conjunctivitis of infectious origin
6. Surgery affecting the eye surface
7. Eye injuries occurred within 3 months before starting the treatment

Date of first enrolment
27/08/2012

Date of final enrolment
24/07/2013

Locations

Countries of recruitment
Hungary

Study participating centre
Department of Ophthalmology, Semmelweis University
Mária str. 39

Budapest
Hungary
1085

Sponsor information

Organisation
Semmelweis University, Department of Ophthalmology

Sponsor details
Mária str. 39.
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1085

Sponsor type
University/education

Website
http://semmelweis.hu/english/department-of-ophthalmology/

ROR
https://ror.org/01g9ty582

Funder(s)

Funder type
Not defined

Funder Name
"Four our Eyesight" Foundation (Budapest, Hungary).

Results and Publications

Publication and dissemination plan
Preliminary data of the 1 month treatment were published in the Hungarian scientific journal Szemészet (Ophthalmology in Hungarian) https://www.researchgate.net/publication/262485247_Examination_of_conservative_treatment_possibility_of_conjunctivochalasis__A_preli

Full data of the 3-month study were published in PLoS ONE: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0132656.

Intention to publish date
14/07/2015

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/07/2015		Yes	No
Protocol (other)			09/02/2023	No	No