

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

<b>Submission date</b> 31/12/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/02/2023	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> 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 globe 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

Dr Huba Kiss

## Contact details

Mária str. 39.  
Budapest  
Hungary  
1085

# 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](mailto: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.  
Budapest  
Hungary  
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\\_preliminary\\_report](https://www.researchgate.net/publication/262485247_Examination_of_conservative_treatment_possibility_of_conjunctivochalasis__A_preliminary_report)

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?
<a href="#">Results article</a>	results	14/07/2015		Yes	No
<a href="#">Protocol (other)</a>			09/02/2023	No	No