

# Examination of the efficacy of Conheal® artificial tears in dry eye patients suffering Sjögren's syndrome

<b>Submission date</b> 28/08/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/09/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/04/2019	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Dry eye complaints are one of the top reasons for visiting ophthalmologists. 12% of the aqueous (water) deficient patients are diagnosed with Sjögren's syndrome, which may cause moderate to severe objective and subjective dry eye symptoms. The aim of the study is to assess whether a preservative-free, inorganic salt-free unit-dose artificial tear, called Conheal® that contains isotonic glycerol and 0.015% hyaluronic acid, can improve vision-related quality of life among dry eye patients suffering Sjögren's syndrome.

### Who can participate?

Adults aged 18 and older who have Sjögren's syndrome.

### What does the study involve?

Participants are asked to use the Conheal® artificial tears 4 times a day for three months. After one and three months of treatment participants undergo ophthalmologic tests and undergo assessment of the subjective symptoms through completing a questionnaire.

### What are the possible benefits and risks of participating?

Participants may benefit from improvements in their symptoms. There are no anticipated risks as Conheal® drop was proven safe in former studies.

### Where is the study run from?

Semmelweis University (Hungary)

### When is the study starting and how long is it expected to run for?

January 2016 to December 2017

### Who is funding the study?

For Our Eyesight Foundation (EU)

Who is the main contact?

Dr Huba Kiss

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Huba Kiss

### ORCID ID

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Examination of the efficacy of Conheal® glycerol and sodium hyaluronate containing artificial tears in dry eye patients suffering Sjögren's syndrome

### 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 improves the objective and subjective dry eye symptoms in patients suffering Sjögren's syndrome after one and three months of treatment.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Semmelweis University Regional and Institutional Committee of Science and Research Ethics, 16 /12/2015, ref: 265/2015

### Study design

Single-centre interventional trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Moderate objective and subjective dry eye symptoms as a consequence of the dry eye disease caused by Sjögren's syndrome.

## 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. There was only one active treatment arm with the study drug.

Participants are followed up at one and three months with ophthalmologic tests are performed and symptoms are assessed using a questionnaire.

## Intervention Type

Drug

## Phase

Phase II

## Drug/device/biological/vaccine name(s)

Conheal® eye drops (provided by Pannonpharma Ltd., Pécsvárad, Hungary)

## Primary outcome(s)

Decrease of the eye surface (lissamine green) staining is measured using the Oxford scheme grade at 1 and 3 months of treatment.

## Key secondary outcome(s)

1. Reduction of lid parallel conjunctival folds is measured using the slit lamp and the Höh classification at one and three months
2. Decrease of Ocular Surface Disease Index (OSDI) is measured using Ocular Surface Disease Index (OSDI) questionnaire score at one and three months
3. Tear production is measured using Schirmer's tests at three months

## Completion date

30/01/2017

## Eligibility

### Key inclusion criteria

1. Female and male patients older than 18
2. Lid parallel conjunctival folds (LIPCOF) degree 1 or higher)
3. Lissamine green staining of minimum grade 1 or higher on the Oxford Scheme grade
4. Decreased production of aqueous tear
5. Sjögren's syndrome

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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 or eye injuries occurred within 3 months before starting the treatment

**Date of first enrolment**

01/02/2016

**Date of final enrolment**

24/10/2016

**Locations****Countries of recruitment**

Hungary

**Study participating centre**

**Semmelweis University**

Department of Ophthalmology

Mária str. 39

Budapest

Hungary

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**Sponsor information**

## Organisation

Semmelweis University

## ROR

<https://ror.org/01g9ty582>

## Funder(s)

### Funder type

Charity

### Funder Name

For Our Eyesight Foundation

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Huba Kiss at [kisshuba@gmail.com](mailto:kisshuba@gmail.com)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>		18/09/2017	02/04/2019	No	No