

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

Submission date 28/08/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/09/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/04/2019	Condition category 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

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Additional identifiers

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

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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

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		18/09/2017	02/04/2019	No	No