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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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/09/2017	**Overall study status** Completed	
Last Edited 02/04/2019	**Condition category** Eye Diseases	

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 end 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

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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 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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Secondary outcome measures
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

Overall study start date
04/01/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
21

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
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Sponsor information

Organisation
Semmelweis University

Sponsor details
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Sponsor type
Not defined

ROR
https://ror.org/01g9ty582

Funder(s)

Funder type
Charity

Funder Name
For Our Eyesight Foundation

Results and Publications

Publication and dissemination plan

Planned publication of the results in PLoS one.

Intention to publish date
01/12/2017

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