Original Hungarian language study protocol for the examination of Examination of the efficacy of Conheal® glycerol and sodium hyaluronate containing artificial tears in dry eye patients suffering Sjögren's syndrome

Approved by the Semmelweis University Regional and Institutional Committee of Science and Research Ethics (permission No. 265/2015).

The experimental preparation

0.15 mg/ml sodium-hyaluronate glycerol, Carbomer 981

Package As sterile eye drops prepared by Pannonpharma Co.

Inclusion of patients

a) approximately 20 persons
b) recruited from the patients of the general outpatient unit of the Department of Ophthalmology of the Semmelweis University

Inclusion criteria

a) volunteer above 18 years of age
b) having a LIPCOF degree of 1 or higher
c) having an epithelial injury of I. or higher in the Oxford scale measured by lissamine green staining
d) decreased tear production
e) diagnoses of Sjögren's syndrome

Exclusion criteria

a) pregnancy, lactation
b) pterygium
c) prolonged treatment with eye drops, other than artificial tears
d) active allergic keratoconjunctivitis
e) current keratitis or conjunctivitis of infectious origin
f) surgery affecting the eye surface, as well as eye injuries occurred within 3 months before starting the treatment.

Study protocol

Enrolment and first examination

The enrolled patients have an ophthalmological examination at the general outpatient department of the Department of Ophthalmology, Semmelweis University. During the examination, the uncorrected and best corrected visual acuity are recorded, and the anterior segment of the eye is examined by a slit lamp. Those patients, that may be enrolled into the trial are informed about the study, and after their questions are answered, they are asked to sign an informed consent. At the first visit, the subjective symptoms of the patients are recorded by the help of the Ocular Surface Disease Index (OSDI) questionnaire. The patient history is recorded. The lid-parallel conjunctival folds (LIPCOF) and the lissamine green staining of the eye surface are graded, ant the tear production is measured with Schirmer's test after applying eye drop anaesthesia (oxybuprocain).

The patient receives the Conheal® eye drops. The trial is unmasked, the patients know, what the eye drop contains. The advised frequency of the eye drop use, and the correct technique is described to the patients in details.

Follow-up after one and three months of active treatment

The tests of the first visit are repeated (OSDI, LIPCOF, lissamine), the Schirmer's test is performed again only at the three months visit. We also ask the patients about their opinion of the artificial tears, or if any adverse events had occurred, or if they perceived any changes. The follow up visits are held at the end of the first end the third month of the active treatment. The planned examination methods are widely used and accepted in the international and Hungarian ophthalmological practice. The examinations and sample collections of the study will be performed at the Department of Ophthalmology of the Semmelweis University.

Information of patients and written informed consent

The patient will be informed on the aim of the study, on the circumstances and protocol of measurements. Data of examinations will be recorded on a separate page where the name of the patient is not included only a randomly generated code/number.

Assessment of statistical analysis

At the end of the study we will examine the data using non-parametric t-probes and correlation tests.