

# Contributions to diagnosis and management of dry eye diseases: a systematic and stepwise approach.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Ocular infections, irritations and inflammations
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON41930

### Source

ToetsingOnline

### Brief title

Contributions to diagnosis and management of dry eye diseases.

### Condition

- Ocular infections, irritations and inflammations

### Synonym

Dry eye diseases, tearfilm disorders

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Oogheelkundig Medisch Centrum Zaandam

**Source(s) of monetary or material Support:** Oogheelkundig Medisch Centrum Zaandam;Cornea Research Fonds.

## Intervention

**Keyword:** Evaporative, Non evaporative, sialic acid, Tes spectacles

## Outcome measures

### Primary outcome

The evaporation rate, and the dew point, Sialic acid concentration, number of goblet cells.

### Secondary outcome

subjective extent to which the patient experiences symptoms (McMonnies questionnaire, VAS scale), the Schirmer test.

## Study description

### Background summary

Dry eye is a frequent problem in the ophthalmic practice. The problem is complex in nature. There are many diagnostic tests described, most tests, however, do not provide insight into the dynamic nature of the tear film. Because the diagnosis is made on history grounds therapeutic measures are not optimal. In recent decades, there is a discrepancy between the physical - chemical research of the tear film and its clinical applications. This study added two parameters that may provide insight into the pathophysiology of dry eye: Sialic acid concentration in tears and Tes Glasses (Tear Evaporation Sensing Spectacles). Tes glasses are modified spectacles that measure the evaporation of tears. In this way we want to obtain a division between evaporative and non - evaporative dry eye. The research design of the pathway dry eyes a decision tree is developed into a systematic, progressive approach to come from both groups dry eye patients

### Study objective

The major goal of this study is to develop a systematic and stepwise approach for dry eyes. First, it will be evaluated whether Tes glasses are a diagnostic tool for dry eye diseases. Second, it will be evaluated or it can make a distinction between evaporative and non evaporative problem dry eyes. Finally, it is examined whether a decrease in sialic acid and a decrease in the number

of goblet cells is appropriate in those with a non-evaporative dry eye problem.

### **Study design**

The research design consists of a prospective study in dry eye patients while ensuring a diagnostic value of a new instrument is tested to determine the evaporation speed of the tear film. For this, the sensitivity and specificity of the glasses Tess is determined. With the Tes spectacles we will make a distinction between evaporative and non-evaporative dry eyes.

In the group of subjects with dry eyes, a Sialic Acid concentration will be announced in combination with a impression cytology of the Conjunctiva to determine the number of goblet cells.

### **Study burden and risks**

this is a no-risk trial. The instruments used, pose no danger to the patient.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

## Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Inclusion criteria persons without dry eyes: age > 18 years, never have symptoms of dry eyes (scored at the Mcmonnies questionnaire) , Osmolarity < 308.

Inclusion criteria persons with dry eyes: age > 18 years, symptoms of dry eyes (scored on the Mcmonnies questionnaire), Osmolarity > 308.

## Exclusion criteria

Exclusion criteria for persons with and without dry eye symptoms: eye surgery, including refractive and plastiv surgery, herpes simplex infections, allergic constituion, antiglaucoma therapy, contact lens wearers, visual acuity < 0.1, chemotherapy treatment.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Basic science

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2015
Enrollment:	370
Type:	Anticipated

## Ethics review

Approved WMO  
Date: 24-02-2015  
Application type: First submission  
Review commission: METC Slotervaartziekenhuis en Reade (Amsterdam)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL52184.048.15