

# Testing of a new measurement procedure for dry eye diagnosis on patients and healthy subjects

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| <b>Submission date</b><br>19/12/2020   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>24/12/2020 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>05/01/2024       | <b>Condition category</b><br>Eye Diseases         | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims:

This study investigates whether the diagnosis of dry eyes and the determination of the degree of severity of dry eyes can be improved by taking measurements with a new type of device in addition to the usual examination. This device determines several values that are important for assessing the severity of dry eyes. This could specify and accelerate the diagnosis of dry eyes in the future.

### Who can participate?

Anyone who is likely to have dry eyes (typical symptoms) can take part. Healthy test subjects can also take part, whose data will serve as comparison values. All participants must have signed the declaration of consent beforehand. Persons who are not yet of legal age or who are subject to guardianship are not allowed to participate. Pregnant and breastfeeding women are also not allowed to participate.

### What does the study involve?

Participants will first be asked some general health questions. A questionnaire will also be filled out, to record the possible symptoms of dry eyes. This study will include people in the study who either show the typical symptoms of dry eyes or have no symptoms at all (control subjects).

Further measurements will be carried out during an ophthalmological consultation if participants have the typical symptoms of dry eyes. First, the data is recorded with a new device. Then the measurements will be made using conventional methods.

The data generated by the new device can be compared with those from the conventional investigation methods.

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

Participating in this study means that additional examinations will be carried out on attendees. Those examinations may be able to address and describe the possible problem of dry eyes more precisely.

Participation in this study is not associated with any additional risks. The light used is comparable to the slit lamp examination and can be felt to be somewhat bright.

Where is the study run from?

The Eye Clinic of Lucerne Cantonal Hospital (Switzerland)

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

November 2020 to December 2021

Who is funding the study?

The Eye Clinic of Lucerne Cantonal Hospital (Switzerland)

Who is the main contact?

Dr Philipp B. Bänninger

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## Contact information

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Public, Scientific

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## **Additional identifiers**

### **Protocol serial number**

2020-002

## **Study information**

### **Scientific Title**

Evaluation of non-invasive automatic measurement protocol for dry eye diagnosis in patients with dry eye disease and control subjects

### **Acronym**

DED trial

### **Study objectives**

The accuracy of dry eye disease diagnosis is improved by applying a new automated non-invasive measurement protocol (IDRA system, SBM Sistemi, Turin, Italy) as compared to routine diagnostic procedures.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 28/12/2020, Ethikkommission Nordwest- und Zentralschweiz (EKNZ) (Hebelstrasse 53, Basel, CH-4056, Switzerland; +41 61 268 13 51; eknz@bs.ch), ref: 2020-02648

### **Study design**

Single-centre cross-sectional diagnostic accuracy study

### **Primary study design**

Observational

### **Study type(s)**

Diagnostic

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

Dry eye syndrome, dry eye disease

### **Interventions**

Tear film condition will be explored in both patients showing dry eye disease (DED) symptoms and control subjects. Non-invasive tear film break-up time, tear meniscus height, lipid layer interferometry, eye blink quality, and infrared meibography will be measured using the IDRA system and compared to results from the established examination protocol (including Ocular Surface Disease Index<sup>®</sup>, tear film break-up time, biomicroscopic slit lamp examination, meibomian dysfunction testing, corneal staining, and Schirmer's test). Participants will be examined for a total duration of 50 min.

## **Intervention Type**

Device

## **Phase**

Not Applicable

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

IDRA system

## **Primary outcome(s)**

1. Classification performance (the proportion of subjects with dry eye disease correctly classified with a positive index test result and the proportion of healthy subjects correctly classified with a positive index test result) measured using the IDRA system to assess non-invasive tear film break-up time (NIBUT) at a single time point

## **Key secondary outcome(s)**

1. Classification performance of lipid layer interferometry measured using the IDRA system at a single time point
2. Classification performance of tear meniscus height measured using the IDRA system at a single time point
3. Classification performance of meibography measured using the IDRA system at a single time point
4. Classification performance of routine diagnostic procedures including tear film break-up time, biomicroscopic slit lamp examination, meibomian dysfunction testing, corneal staining, and Schirmer's test at a single time point

## **Completion date**

04/05/2021

## **Eligibility**

### **Key inclusion criteria**

All participants:

1. Aged between 18 and 79 years
2. Given consent and signed the consent form declaration

Patients:

1. Ocular Surface Disease Index (OSDI©) score  $\geq 13$
2. At least one of the following:
  - 2.1. Image result for tear break-up time (TBUT) of  $\leq 10$  sec
  - 2.2. Corneal staining grading  $\geq$  grade II
  - 2.3. Schirmer test  $\leq 10$  mm in 5 min

Control subjects:

1. OSDI© score  $< 13$
2. Absence of sensitivity to light, ocular grittiness, ocular pain or soreness, blurred vision, poor vision, and eye redness

### **Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

75

**Key exclusion criteria**

1. Eyelid deformities or eyelid motility disorders (such as incomplete lid closure, entropium, ectropium, hordeola, or chalazia)
2. Previous ocular disease leaving sequelae or requiring current topical eye therapy
3. Active ocular allergy
4. Known hypersensitivity to sodium fluorescein or oxybuprocaine
5. LASIK or PRK surgery performed
6. Punctal plugs or cauterization within the past 30 days
7. Abnormality of nasolacrimal drainage
8. Pregnancy or lactation
9. Systemic disease known to affect tear production or loss, diagnosed or being instable within the past 30 days
10. Started or changed dose of chronic systemic medication known to affect tear production within the past 30 days
11. Any eye drops within the past 8 h
12. Contact lens worn within the past 8 h

**Date of first enrolment**

01/01/2021

**Date of final enrolment**

27/04/2021

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

Switzerland

**Study participating centre**

**Eye Clinic of Lucerne Cantonal Hospital (Augenlinik des Luzerner Kantonsspitals)**

Luzerner Kantonsspital

Spitalstrasse

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6000

## Sponsor information

### Organisation

Luzerner Kantonsspital

### ROR

<https://ror.org/02zk3am42>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Luzerner Kantonsspital

## Results and Publications

### Individual participant data (IPD) sharing plan

The study protocol and individual participant data that underlie the results reported in the article, after deidentification will be available upon request to [janosch.rinert@bluewin.ch](mailto:janosch.rinert@bluewin.ch). To gain access, data requestors will need to sign a data access agreement. Data will be available beginning 3 months and ending 5 years following article publication to researchers who provide a methodologically sound proposal for whom the analysis of the data will aid in achieving the aims of the approved proposal.

### IPD sharing plan summary

Available on request

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 21/04/2022   | 29/06/2022 | Yes            | No              |