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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
19/12/2020		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
24/12/2020	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
05/01/2024	Eye Diseases			

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?
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Contact information

Type(s)

Public, Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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©, 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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

IDRA system

Primary outcome measure

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

Secondary outcome measures

- 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

Overall study start date

01/11/2020

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 ≥13
- 2. At least one of the following:
- 2.1. Image result for tear break-up time (TBUT) of ≤10 sec
- 2.2. Corneal staining grading ≥grade II
- 2.3. Schirmer test ≤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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

35 patients, 31 control subjects

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. Abormality 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 (Augenklinik des Luzerner Kantonsspitals)

Luzerner Kantonsspital Spitalstrasse Lucerne 16 Switzerland 6000

Sponsor information

Organisation

Luzerner Kantonsspital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

https://www.luks.ch/

ROR

https://ror.org/02zk3am42

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Luzerner Kantonsspital

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2021

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. 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?
Results article		21/04/2022	29/06/2022	Yes	No