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

Submission date 19/12/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/12/2020	**Overall study status** Completed	
Last Edited 05/01/2024	**Condition category** 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?
Dr Philipp B. Bänninger
philipp.baenninger@gmail.com

Contact information

Type(s)
Public, Scientific

Contact name
Dr Philipp B Bänninger

ORCID ID
https://orcid.org/0000-0001-8118-2464

Contact details
Eye Clinic of Lucerne Cantonal Hospital (Augenklinik des Luzerner Kantonsspitals)
Spitalstrasse
Lucerne 16
Switzerland
6000
+41 41 205 34 10
philipp.baenninger@gmail.com

Type(s)
Public, Scientific

Contact name
Mr Janosch Rinert

ORCID ID
https://orcid.org/0000-0003-2616-0291

Contact details
Eye Clinic of Lucerne Cantonal Hospital (Augenklinik des Luzerner Kantonsspitals)
Spitalstrasse
Lucerne 16
Switzerland

6000
+41 79 575 71 61
janosch.rinert@bluewin.ch

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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©, 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 ≥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

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. 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

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. 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