Dry Eye Disease: assessment of existing diagnostic methods

Published: 27-03-2023
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To evaluate existing an currently practiced methods for assessing ocular surface characteristics of DED in order to evaluate their characteristics and comparability.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ocular infections, irritations and inflammations
Study type	Observational non invasive

Summary

ID

NL-OMON53487

Source
ToetsingOnline

Brief title
Dry Eye Disease: assessment of existing diagnostic methods

Condition

- Ocular infections, irritations and inflammations

Synonym
dry eye disease

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnostics, Dryness, Evaluation, Opthalmology

Outcome measures

Primary outcome

Tear osmolarity values and tear film characteristics of DED and scoring of a

questionnaire for DED.

Secondary outcome

Correlation between tear osmolarity, tear film characteristics and DED scoring

via questionnaire.

Study description

Background summary

Dry eye disease (DED) is defined as a multifactorial disorder of the ocular surface characterized by a loss of homeostasis of the tear film. This results in ocular symptoms such as discomfort, sensations of grittiness or pain, and visual disturbance. DED is the most common reason for seeking medical ocular care and has a growing prevalence as the global population ages. Historically there has been a lack of a standardized definition and classification system for DED. The international report on DED by the Tear film and Ocular surface Society (TFOS) has advised which parameters should be assessed for diagnosing DED. There exist multiple methods to assess these parameters and newer methods are being developed. However, no advice is given on which method is preferred.

Study objective

To evaluate existing an currently practiced methods for assessing ocular surface characteristics of DED in order to evaluate their characteristics and comparability.

Study design

Single-center prospective observational study

Study burden and risks

No risks are associated with participation

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- 18 years of age or older
- capable of giving informed consent
- Able to undergo visual acuity measurements, slit lamp examination, Schirmer II test and to complete a Dutch questionnaire
- Able to undergo measurements with the I-Pen and IDRA devices

Exclusion criteria

- Ophthalmological comorbidities which affect the ocular surface
- Comorbidities with possible ophthalmological consequence
- Previous diagnosis of DED, as diagnosed by a professional clinician
- History of ophthalmological surgical interventions

- Usage of lubricating eye drops or topical drugs for the eye in the last 30 days

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-08-2023
Enrollment:	17
Type:	Actual

Medical products/devices used

Generic name:	I-Pen tear osmolarity meter; IDRA ocular surface analyser; Slit-lamp; Schirmer II test strips
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-03-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL82559.018.22