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Development and validation of a clinical severity scale in persons with watery eyes

Submission date
06/09/2018

Recruitment status
No longer recruiting

Registration date
06/11/2018

Overall study status
Completed

Last Edited
05/06/2023

Condition category
Eye Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Having watery eyes is common. There are many causes but in some people it can be improved with surgery or by using eye drops. In some patients the excess watering might only be a mild nuisance, while in others it may dramatically affect their everyday life. Some patients may even get recurrent infections and need antibiotics or hospital-based treatment. With such a wide range of severity, it is useful for doctors to have a way to classify patients and prioritise them accordingly, so that the people who most need treatment receive it. A grading scale called the TEARS score has been developed for this very purpose. The TEARS score might also be used to tell whether treatment has been beneficial. It might also be able to help doctors to decide which treatments are most effective. By talking to both doctors and patients, it has been designed to address several important features of watery eyes. The scale considers not only symptoms, but also the effect of watery eyes on a person's day-to-day life and on their health. The aim of this study is to test the TEARS score and make sure that it is reliable, useful and measures what it was designed to.

Who can participate?
Patients aged over 18 who have been referred to a specialist clinic with watery eyes

What does the study involve?
Participants are asked a few questions at the time of their initial visit and complete some short questionnaires. The whole process is expected to take 15 minutes. This process is repeated at a second visit a few months later. If participants undergo surgery for watery eyes, this second visit takes place a few months after the procedure. If participants are discharged from the eye clinic at their initial visit, they may be contacted by telephone for the final consultation. Some patients may be started on eye drops or even undergo surgery after they meet their consultant. Any decision to undergo surgery or to be started on any treatment is made prior to the participant's involvement in this study. Their involvement in this study does not determine or influence the proposed treatment or influence any future decisions on treatment.

What are the possible benefits and risks of participating?
There are no specific benefits of taking part, but the results of this study may help shape the treatment of future patients. The researchers recognise that the participants' time is important

to them and very much value the time they can spend as part of this important research. They also recognise the difficulty and cost involved in getting to the eye clinic, and will make every effort to make appointments as efficient as possible and at a time that is convenient. Where possible, the research data will be collected at the time of a routine eye clinic review.

Where is the study run from?
Queen Victoria Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2018 to December 2020 (updated 10/05/2021, previously: December 2019)

Who is funding the study?
1. Primarily investigator initiated and funded
2. Merz Pharma UK
3. Thea Pharmaceuticals Ltd

Who is the main contact?
1. Mr Raman Malhotra
2. Dr Christopher Schulz

Contact information

Type(s)
Scientific

Contact name
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Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.8

Study information

Scientific Title
Development and validation of the TEARS grading scale: a clinical tool for grading the severity of epiphora

Study objectives
Epiphora (watery eye) is a common complaint of patients presenting to the oculoplastic clinic. There is a spectrum of clinical severity in patients with epiphora. While in some, the epiphora represents no more than a tolerable nuisance, in others it significantly affects their quality of life. At the more severe end of the severity spectrum, some cases require repeat medical attendances and hospital admissions for systemic infection. While various tools have been used to evaluate symptom severity, to date there is no valid grading scale that also considers the patient's functional status and quality of life as well as the clinical consequences on both patients and healthcare providers. There is a need for clinicians and healthcare commissioners to have a valid grading scale that allows the prioritisation of patients for surgical intervention based on both disease severity and the likelihood of success. The ‘TEARS scale’ was developed through extensive literature review, patient focus groups and consultation with an expert panel of consultant ophthalmologists. Disease severity is graded based on 4 subscales: symptom frequency, the effects on patients and healthcare providers, patients’ functional status, and the compounding effect of ocular surface disease. This prospective study aims to evaluate the reliability and validity of the TEARS scale in a population of patients presenting to a specialist oculoplastic clinic with epiphora.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester West Research Ethics Committee, 05/11/2018, REC ref: 18/NW/0769

Study design
Observational validation cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
Epiphora (watery eye)

Interventions
This is an observational study. It is expected that some participants will undergo medical or surgical intervention as part of their planned medical care (but not determined or influenced by their inclusion in the study).

After the participant has entered the study, the treating clinician will complete the TEARS scale in consultation with the participant. Data will also be collected about the diagnostic cause of epiphora, previous surgery, and whether surgery is planned. At the same visit, a second clinician or member of the study team will again complete the TEARS scale after a minimum of 15 minutes. This will allow the evaluation of inter-observer reliability of the TEARS scale. The participant will be asked to complete two self-administered questionnaires (Lac-Q and WEQOL). The participant's care pathway will continue as planned with their consultant regardless of their involvement in this observational study. Any participants undergoing surgical intervention as part of this plan will be reviewed within a period of 3-6 months following their intervention as part of their routine clinical care. Non-surgical participants who are still under routine follow-up by their clinical team will be reviewed 3-6 months after the date of their baseline visit. If participants have already been discharged from routine clinical care, a telephone-based review will be conducted by a member of the research team. At this follow-up review (either face-to-face or telephone-based), either their clinician or a member of the research team will complete the TEARS scale with the patient. The participant will complete three self-reported questionnaires (WEQOL, Lac-Q and GBI). Following completion of this review, the participant will exit the study.

Intervention Type
Other

Primary outcome measure
The TEARS scale will be completed at baseline by two clinicians and at the follow-up appointment (3-6 months after any intervention). The TEARS scale has been developed and gone through multiple iterations by our group through extensive literature review, patient focus groups and consultation with an expert panel of consultant ophthalmologists. Disease severity is graded based on 4 subscales: symptom frequency, the effects on patients and healthcare providers, patients' functional status, and the compounding effect of ocular surface disease. A fifth subscale is used postoperatively to record patient-reported success as a percentage.

Secondary outcome measures

1. The Watery Eye Quality of Life (WEQOL) score is a 10-item patient-administered questionnaire that takes most people approximately 5 minutes to complete. This is a disease-specific quality of life tool whose development is evidence-based and is undergoing further validation studies in patients with surgically-amenable epiphora.
2. The Lacrimal Symptom Questionnaire (Lac-Q) is a 9-item patient-administered questionnaire that takes approximately 5 minutes to complete. This is a validated scale of symptom severity and social impact that has to date been used in published studies involving approximately 400 patients.
Both the WEQOL and Lac-Q will be completed at baseline and again at follow-up 3-6 months after any intervention.
3. The Glasgow Benefit Inventory (GBI) is a validated 18-item questionnaire that has been used in patients with epiphora to evaluate changes in psychological, social and physical well-being. The GBI will be completed at the final study visit 3-6 months after any intervention.

Overall study start date
20/03/2018

Completion date
01/12/2020

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Diagnosed by an ophthalmologist with experience in lacrimal pathology as having a cause of epiphora amenable to surgical or non-surgical intervention (including tear outflow obstruction, excess eyelid laxity, eyelid malposition, lacrimal hypersecretion or reflex epiphora secondary to evaporative dry eye)
3. Participant is willing and able to give informed consent for participation in the study
4. Participant is fluent in written and spoken English language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
107

Total final enrolment
136

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
07/11/2018

Date of final enrolment
19/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Victoria Hospital
Holtye Road
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United Kingdom
RH19 3DZ

Sponsor information

Organisation
Queen Victoria Hospital

Sponsor details
Holtye Road
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Sponsor type
Hospital/treatment centre

Website
http://www.qvh.nhs.uk

ROR
https://ror.org/01ywpxj09

Funder(s)

Funder type
Other

Funder Name
Primarily investigator initiated and funded

Funder Name
Merz Pharma UK

Funder Name
Thea Pharmaceuticals Ltd

Results and Publications

Publication and dissemination plan
To be published in peer-reviewed journal and presented at national and international scientific meetings.

Intention to publish date
30/06/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2022	05/06/2023	Yes	No
HRA research summary			28/06/2023	No	No