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Can we improve knowledge of patients with keratoconus with educational material?

Submission date 06/01/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/01/2020	**Overall study status** Completed	
Last Edited 11/06/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aim:
Keratoconus is an eye disease in which the normally round cornea thins and begins to bulge into a conical shape. This cone shape deflects light as it enters the eye and therefore causes distortion of vision. This study intends to investigate the benefit of educational material to improve the patient's knowledge of the disease.

Who can participate?
Everyone who was previously diagnosed with keratoconus, who is older than 18 years can participate in the study at the Eye clinic of Cantonal Hospital of Lucerne.

What does the study involve?
The interventional group of patients will watch an educational material and answer control questions about this material before the consultation with the eye doctor. The patients in the interventional as well as the control group will fill out a questionnaire assessing their keratoconus knowledge after the consultation.

Benefits and risks of participating?
There are no risks of participating but the benefit for the participants is a better understanding of the disease, which will help the participant to make decisions on treatment options together with the doctor.

Where is the study run from?
The special corneal clinic at the Eye Clinic of Cantonal Hospital of Lucerne (Switzerland)

When is the study starting and how long is it expected to run for?
October 2019 to July 2020

Who is funding the study?
The Eye Clinic of the Cantonal Hospital of Lucerne (Switzerland)

Who is the main contact?
Philipp Baenninger, philipp.baenninger@luks.ch

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2020-001

Study information

Scientific Title
The effect of an educational intervention to improve knowledge of patients with keratoconus attending a pre-intervention consultation – a randomized controlled trial

Study objectives
Keratoconus is a progressive, ectatic corneal disease in which the normally round cornea thins and begins to bulge into a conical shape. This cone shape deflects light as it enters the eye on its way to the light-sensitive retina and causes distortion of vision.
This study intends to investigate the benefit of an educational measure prior to a consultation with a physician regarding the knowledge of keratoconus. This will help us to further develop and design the information material for keratoconus patients. By improving the knowledge about keratoconus we hope to indirectly improve the decision making of keratoconus patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)
The local ethical committee reviewed the protocol of this study and found that it would not fall under the Human Research Act

Study design
Single-centre single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Keratoconus

Interventions
Measurements and Randomization:
Potentially eligible patients treated at the corneal clinic of the LUKS will be informed about the existence of the study by the administrative staff of the clinic. If a patient is interested to take part, written informed consent will be sought for study inclusion and usage of clinical data. All participants will be informed that they have the right to withdraw from the study at any time without any disadvantage and without having to provide their reason for this decision. Subjects will not undergo any study specific procedures until they have provided written consent by signing the informed consent form, which will also be signed by the person obtaining the consent.

Participating patients will be randomized at the clinical trial centre (outside the hospital) using the Stata 16.0 randomization routines. Randomization will be made with a 1:1 allocation ratio and using blocks of 2 and 4. The randomization list will be kept at the trial centre (concealed) and caregivers at the consultation will be blinded to the allocation.

Prior to the consultation of the interventional group, standardized oral information about keratoconus will be provided via the multifaceted educational material. The time taken to digest the material and answer the control questions will not exceed 10 min.

Both groups will spend another 5 min to fill out the questionnaire assessing their keratoconus knowledge after the consultation.

Intervention:
The educational material shows different animated scenes giving the same standardized information on keratoconus as the treating ophthalmologist gives in regular face-to-face consultation. The material was developed in collaboration with members of the medical faculty of the University of Zurich and a group of clinical experts at the eye clinic of the LUKS in January 2020. The duration of the multifaceted educational intervention takes about 5 min.

Control intervention:
Patients randomized to the non-interventional group will receive a standard consultation representing best practice.

Intervention Type
Behavioural

Primary outcome measure
Knowledge on keratoconus as assessed by an assessment form containing six multiple-choice questions designed according to information gathered in the previous minimum keratoconus study. Distribution of baseline parameters will be assessed and parameters deviating 10% or more between groups will be entered as covariates for the efficacy analyses to reduce the risk for confounding. The effects of the intervention on the primary outcome will be estimated using regression modeling. The assessment form will be provided directly after the intervention or control material.

Secondary outcome measures
1. Stage of keratoconus
2. Previous treatments for keratoconus
3. Sex, age and highest level of education

These data will also be collected in the assessment form directly after the intervention or control material.

Overall study start date
01/10/2019

Completion date
02/07/2020

Eligibility

Key inclusion criteria
1. Previously diagnosed keratoconus on at least one eye
2. Signed written informed consent

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
40

Total final enrolment
43

Key exclusion criteria
1. Inability to follow the procedures of the study due to i.e. language problems, psychological disorders, dementia etc
2. Aged <18 years
3. Enrolment of the investigator, his/her family members, employees and other dependent persons

Date of first enrolment
01/03/2020

Date of final enrolment
26/06/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
Augenklinik Luzerner Kantonsspital [Cantonal Hospital of Lucerne Eye Clinic]
Spitalstrasse
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Sponsor information

Organisation
Augenklinik Luzerner Kantonsspital [Cantonal Hospital of Lucerne Eye Clinic]

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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
Augenklinik Luzerner Kantonsspital [Cantonal Hospital of Lucerne Eye Clinic]

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The data that support the findings of this study are available from the corresponding author, Philipp Baenninger, upon reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/10/2022	11/06/2025	Yes	No