

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

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<b>Registration date</b> 10/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/06/2025	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## 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

## Contact name

Dr Philipp Baenninger

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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.

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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

Lucerne

Switzerland

6000

## Sponsor information

**Organisation**

Augenklinik Luzerner Kantonsspital [Cantonal Hospital of Lucerne Eye Clinic]

**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

**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?
<a href="#">Results article</a>		24/10/2022	11/06/2025	Yes	No