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Effects of video presented information about Excimer laser therapy on comprehension and satisfaction with informed consent

Submission date
05/05/2017

Recruitment status
No longer recruiting

Registration date
10/05/2017

Overall study status
Completed

Last Edited
07/01/2020

Condition category
Eye Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It is important for patients to provide informed consent prior to undergoing a medical treatment. Informed consent means that patients understand the purpose, benefits, and risks of the treatment. New methods of presenting informed consent, such as using video assistance, multimedia presentations and education classes have been studied in order to try to improve patients understanding and satisfaction with their medical treatments. In ophthalmology (a branch of medicine that looks at eye diseases), effects of different presentation methods on patients' understanding have most commonly been investigated within the IC process of cataract surgery. Research has shown that providing video-assistance for IC has improved the understanding and satisfaction of patients with IC processes. Video-assisted IC processes may also be beneficial for patients who are ametropic (where the eye cannot focus on distant objects) who are undergoing a treatment for this called refractive excimer laser therapy. The aim of this study is to improve patient's knowledgeable refractive excimer laser therapy and evaluate patient's satisfaction with the overall IC processes in order to empower patients to make well informed decisions about their treatments.

Who can participate?
Adults aged 18 and older who attend a consult for refractive excimer laser therapy.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the standard informed consent process. This involves oral and written information about the treatment and a discussion with the ophthalmologist. Those in the second group receive informed consent through the help of video to present the information in addition to the standard informed consent process. Participants then fill out a questionnaire to assess their knowledge, satisfaction, anxiety levels and if the duration of the consultant was as expected.

What are the possible benefits and risks of participating?
Participants may benefit from feeling more empowered when they make an informed decision about treatment. There are no notable risks with participating

Where is the study run from?
Cantonal Hospital Lucerne, Eye Clinic (Switzerland)

When is the study starting and how long is it expected to run for?
January 2017 to January 2019

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

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effects of video presented information about excimer laser therapy on ametropic patients' comprehension and satisfaction with the informed consent process: A randomized controlled trial

Study objectives
1. Patients' knowledge about excimer laser therapy will be more in the intervention compared to the non-intervention group
2. Patients' satisfaction with provided information will be higher in the intervention (video-based information) compared to the non-intervention (conventional oral information) group
3. Anxiety levels will not defer between intervention and non-intervention group
4. Perceived contact time will be higher in the intervention compared to the non-intervention group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Single-centre open randomized parallel controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Excimer laser treatment for ametropia

Interventions
Potentially eligible participants treated at the refractive centre of the cantonal hospital Lucerne (LUKS) are informed about the existence of the study by their treating ophthalmologist. During an initial consultation, the ophthalmologist ask if a the participant is interested in participating in the study. Participants are asked to give written informed consent for study inclusion and usage of clinical data.

Participants are randomised either to the non-interventional group (verbal conventional informed consent) or to the interventional group (verbal and video-assisted interventional informed consent) prior to their refractive excimer laser therapy. The randomisation is pre-stratified for age (under 38 years versus older than 38 years), due to the management and expectations of participants approaching the phase of presbyopia might slightly differ. Randomisation is done using “REDCap” in a 1:1 allocation into the non-/intervention group respectively. The randomisation is not blinded.

Non-interventional group: Participants receive a standard consultation for informed consent done to the standard level of care. This involves information about the treatment in oral and written form. The informed consent process includes information about benefits, risks, adverse events of and reasonable alternatives to refractive excimer laster therapy. In addition, ophthalmologists address individual factors of a specific patient that might affect therapy outcome. Finally, ophthalmologists answers patients’ remaining uncertainties and clarify ambiguities.

Interventional group: Participants receive a verbal and video-assited informed consent process. This includes standardised oral information about refractive excimer laser therapy exchanged by a video. Similar to the non-interventional group, standardised information about the intervention in written form is also provided. Ophthalmologists also address individual factors of a specific patient that might affect therapy outcome and answer patients’ formerly unanswered questions.

After the consultation, all participants are asked to fill out a paper-based questionnaire, assessing knowledge, satisfaction, anxiety levels and if the duration of the consultation (contact time between ophthalmologist and patient) was as expected.

Intervention Type
Behavioural

Primary outcome(s)
Patients knowledge is measured using five multiple choice questions with five statements after the consultation.

Key secondary outcome(s))
1. Patients' satisfaction is measured using a questionnaire after the consultation.
2. Anxiety levels is measured using a subpart of the State-Trait Anxiety Inventory 42 after the consultation.
3. Perceived contact time measured using a questionnaire after the consultation.

Completion date
01/01/2019

Eligibility

Key inclusion criteria
1. Patients assessing refractive excimer laser therapy for ametropia at the refractive centre of the LUKS will be evaluated at their initial visit for study inclusion
2. Signed written informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
01/06/2017

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
Switzerland

Study participating centre
Cantonal Hospital Lucerne, Eye Clinic
Augenklinik
Luzerner Kantonsspital
Spitalstrasse
Schweiz
Lucerne
Switzerland
6000

Sponsor information

Organisation
Augenklinik Luzerner Kantonsspital [Cantonal Hospital Lucerne Eye Clinic]

ROR
https://ror.org/02zk3am42

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cantonal Hospital Lucerne, Eye Clinic

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Lucas Bachmann (bachmann@medignition.ch)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes