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

Submission date	Recruitment status	[X] Prospectively registered
05/05/2017	No longer recruiting	[] Protocol
Registration date	Overall study status	[] Statistical analysis plan
10/05/2017	Completed	[_] Results
Last Edited	Condition category	Individual participant data
07/01/2020	Eye Diseases	[] 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? Dr Philipp B. Bänninger philipp.baenninger@luks.ch

Contact information

Type(s) Scientific

Contact name Dr Philipp Baenninger

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

 Patients' satisfaction with provided information will be higher in the intervention (videobased information) compared to the non-intervention (conventional oral information) group
Anxiety levels will not defer between intervention and non-intervention group
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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s) Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 prestratified 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 measure

Patients knowledge is measured using five multiple choice questions with five statements after the consultation.

Secondary outcome measures

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.

Overall study start date

01/01/2017

Completion date

01/01/2019

Eligibility

Key inclusion criteria

 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
Signed written informed consent form

Participant type(s) Patient

Age group Adult

Sex

Both

Target number of participants 43 paricipant in each trial arm respectively.

Key exclusion criteria

Inability to follow the procedures of the study due to i.e. language problems, psychological disorders, dementia etc
Aged < 18 years
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]

Sponsor details

Spitalstrasse Lucerne Switzerland 6000

Sponsor type

Hospital/treatment centre

ROR https://ror.org/02zk3am42

Funder(s)

Funder type Hospital/treatment centre

Funder Name Cantonal Hospital Lucerne, Eye Clinic

Results and Publications

Publication and dissemination plan

Planned publication in an high-impact peer reviewed journal.

Intention to publish date 01/01/2020

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