

Video informed consent for cataract surgery

Submission date 21/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/11/2021	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cataracts occur when changes in the lens of the eye cause it to become less transparent, causing cloudy, blurry, or misty vision. Cataract surgery involves removing the cloudy lens through a small cut in the eye and replacing it with a clear, plastic lens. The aim of this study is to assess the benefits of showing patient education videos to patients considering cataract surgery.

Who can participate?

Patients undergoing cataract surgery for the first time

What does the study involve?

Participants are randomly allocated to either watch the educational video before meeting with their surgeon for counselling, or to just receive face-to-face counseling with their surgeon. Participants are then asked to complete a short questionnaire at the end of their visit to assess their comprehension and satisfaction.

What are the possible benefits and risks of participating?

Participants may learn more about their surgery by viewing a patient education video. No risks are anticipated as the video shown was carefully produced by the American Academy of Ophthalmology.

Where is the study run from?

Gavin Herbert Eye Institute at the University of California, Irvine (USA)

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

June 2017 to September 2017

Who is funding the study?

University of California, Irvine (USA)

Who is the main contact?

Mr Thomas Vo

Contact information

Type(s)

Public

Contact name

Mr Thomas Vo

Contact details

850 Health Sciences Road
Irvine
United States of America
92697

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2017-3626

Study information

Scientific Title

Multimedia-facilitated informed consent for cataract surgery: a randomized controlled trial

Study objectives

Use of patient education videos will reduce the time needed to complete the informed consent process.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board at the University of California, Irvine, 06/08/2017, ref: HS#2017-3626

Study design

Single-centre randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Cataract surgery

Interventions

Patients will be randomized through a coin flip to either view the education video prior to counseling from a surgeon or routine face-to-face counseling with a surgeon alone. Patients will be asked to complete a short questionnaire at the conclusion of their visit that will assess comprehension and satisfaction.

Intervention Type

Other

Primary outcome measure

1. Time to complete the informed consent process, measured at the end of the informed consent process
2. Comprehension and satisfaction, assessed through a self-administered questionnaire at the end of their preoperative appointment (same day)

Secondary outcome measures

No secondary outcome measures

Overall study start date

09/06/2017

Completion date

01/09/2017

Eligibility**Key inclusion criteria**

Any patient undergoing first time phaco cataract surgery for placement of a monofocal lens

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Patients unable to view/hear a video on a tablet device
2. Patient unable to give informed consent
3. Patient unable to speak English

Date of first enrolment

09/06/2017

Date of final enrolment

01/09/2017

Locations**Countries of recruitment**

United States of America

Study participating centre

Gavin Herbert Eye Institute at the University of California, Irvine

United States of America

92697

Sponsor information**Organisation**

Gavin Herbert Eye Institute, University of California, Irvine

Sponsor details

850 Health Sciences Road

Irvine

United States of America

92697

Sponsor type

University/education

ROR

<https://ror.org/04gyf1771>

Funder(s)**Funder type**

University/education

Funder Name

University of California, Irvine

Alternative Name(s)

UC Irvine, Irvine, University of California Irvine, Pacific School of Osteopathy, Pacific College of Osteopathy, Los Angeles College of Osteopathy, California College of Osteopathic Physicians and Surgeons, California College of Medicine, UCI

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

United States of America

Results and Publications

Publication and dissemination plan

Planned publication in an ophthalmology journal.

Intention to publish date

01/09/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as the datasets will not have any value beyond the scope of the study.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/08/2018	26/11/2021	Yes	No