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Video informed consent for cataract surgery

Submission date 21/06/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/06/2017	**Overall study status** Completed	
Last Edited 26/11/2021	**Condition category** Surgery	

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