ISRCTN26680260 https://doi.org/10.1186/ISRCTN26680260

Video-assisted vs conventional surgical informed consent in visceral surgery, a cluster-randomized clinical trial

Submission date
28/10/2025

Recruitment status
No longer recruiting

Registration date
30/10/2025

Overall study status
Completed

Last Edited
30/10/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
This study looks at two different ways of giving patients information before surgery: the traditional face-to-face talk with a doctor, and a video explanation. The goal is to see if using a video can save doctors time while still helping patients understand their surgery and feel satisfied with the information they receive.

Who can participate?
Patients who are having either their gallbladder removed or part of their colon removed at the University Hospital of Würzburg can take part in the study.

What does the study involve?
Participants are randomly placed into one of two groups. One group watches a video that explains the surgery, while the other group receives the usual in-person explanation from a doctor. Afterward, both patients and doctors fill out short questionnaires about how well the information was understood and how satisfied they were. The time spent on each method is also recorded.

What are the possible benefits and risks of participating?
The study may help improve how patients are informed before surgery in the future. There are no known risks from taking part, and all participants still receive the necessary information about their surgery, either by video or in person.

Where is the study run from?
University Hospital of Würzburg in Germany

When is the study starting and how long is it expected to run for?
The study began in September 2023 and is expected to finish in March 2025.

Who is funding the study?
University Hospital of Würzburg in Germany
The educational video used in the study was developed by medudoc education GmbH.

Who is the main contact?
Dr Svenja Leicht, svenja.leicht@web.de

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Video-assisted surgical informed consent, compared to conventional informed consent, reduces physicians' time expenditure while maintaining patient satisfaction and understanding. A cluster-randomized clinical trial

Study objectives
The objective of this study was to compare video-assisted with conventional surgical informed consent in terms of duration, patient understanding, as well as patient and physician satisfaction.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 20/01/2023, Ethics Committee of the Julius-Maximilians-University of Würzburg (Petrinistraße 33a, Würzburg, 97080, Germany; +49 931 31 48315; ethikkommission@uni-wuerzburg.de), ref: 112/22

Study design
Single center interventional cluster-randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Video-assisted versus conventional surgical informed consent before elective surgery

Interventions
Patients in the intervention group receive a video developed by medudoc education GmbH, while the control group receives physician-led informed consent according to the hospital's standard. The duration of both methods is measured using a stopwatch. Patients in both groups complete questionnaires on satisfaction and understanding after the surgical informed consent and postoperatively. Upon study completion, participating physicians also complete a questionnaire to assess their satisfaction.

Randomisation was conducted manually by the study management team to achieve approximately equal numbers in the intervention and control groups.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Physician consultation time measured using a stopwatch at the consultation

Key secondary outcome(s))
Measured at the consultation:
1. Depressivity: PHQ-2
2. General anxiety: GAD-2
3. Surgery-related anxiety: APAIS
4. Illness and treatment beliefs: IPQ-R
5. Patient satisfaction: ZUF-8
6. Patient understanding: self-developed questionnaire
7. Physician satisfaction: self-developed questionnaire
8. Additionally, data on diagnosis, type of surgery, and postoperative pain (assessed via the Numeric Rating Scale, NRS) were extracted from patient records

Completion date
30/03/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Sufficient proficiency in the German language
3. Elective indication for surgery

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
153

Key exclusion criteria
1. Occurrence of postoperative complications classified as grade IV or V according to the Clavien-Dindo classification

Date of first enrolment
01/09/2023

Date of final enrolment
30/03/2025

Locations

Countries of recruitment
Germany

Study participating centre
Uniklinikum Würzburg
Oberdürrbacherstraße 6
Würzburg
Germany
97080

Sponsor information

Organisation
medudoc education GmbH

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsklinikum Würzburg

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated an analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in German		30/10/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes