

‘Video versus face-to-face consultation between patients and their surgeon prior to major gastrointestinal oncological surgery (VIDEOGO): a multicenter, randomized controlled, non-inferiority trial.’

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The VIDEOGO-trial aims to assess whether video consultation (VC) is non-inferior to face-to-face (F2F) consultation in terms of 1) patient satisfaction and 2) information retention regarding the pre-operative consultation for complex...

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20092

Source

NTR

Brief title

VIDEOGO

Health condition

Patients are required to undergo a complex gastrointestinal surgical procedure, defined as one of the following 7 procedures: Gastrectomy (partial or total) Pancreatic resection (right, left, total) Liver resection (minor and major) Total mesorectal Excision (TaTME) and high anterior resection; Segmental colectomy (left, right, sigmoid); Hyperthermic intraperitoneal chemotherapy (HIPEC). Intrathoracic stomach correction

Sponsors and support

Primary sponsor: Amsterdam UMC

Source(s) of monetary or material Support: Citrienfonds

Intervention

Outcome measures

Primary outcome

Primary outcomes are 1) patient satisfaction based on the PSQ-NL questionnaire (a VAS-based questionnaire, detailed in Appendix C) and 2) information retention based on a custom questionnaire (Appendix D).

Secondary outcome

The secondary outcome will be 1) surgeon satisfaction (based on the translated PSQ physician (Appendix E).

Study description

Background summary

The VIDEOGO-trial aims to assess whether video consultation (VC) is non-inferior to face-to-face (F2F) consultation in terms of 1) patient satisfaction and 2) information retention regarding the pre-operative consultation for complex gastrointestinal surgery.

Study objective

The VIDEOGO-trial aims to assess whether video consultation (VC) is non-inferior to face-to-face (F2F) consultation in terms of 1) patient satisfaction and 2) information retention regarding the pre-operative consultation for complex gastrointestinal surgery. The hypothesis is that VC is not inferior to F2F.

Study design

All primary and secondary outcomes will be measured within 48 hours after the pre-operative consultation.

Intervention

Video consultation in the pre-operative consultation for complex gastrointestinal surgery.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients at least 18 years old 2. Patients with a scheduled appointment at the surgical outpatient clinic to explain a complex gastrointestinal surgical procedure, defined as one of the following 7 procedures: Gastrectomy (partial or total) Pancreatic resection (right, left, total) Liver resection (minor and major) Total mesorectal Excision (TaTME) and high anterior resection; Segmental colectomy (left, right, sigmoid); Hyperthermic intraperitoneal chemotherapy (HIPEC). Intrathoracic stomach correction 3. Patients capable and willing to interact with their surgeon both via video- and face-to-face consultation. 4. Patients who have never physically met the surgeon, prior to the pre-operative consultation. 5. Patients able to provide oral informed consent for their surgical procedure.

Exclusion criteria

1. Patients without access to an electronic device and /or internet connection and/or otherwise unable or unwilling to start or maintain a video consultation with their surgeon 2. Patients who are not willing to activate their electronic patient portal as this is required for video consultation. 3. Patients without sufficient sight or hearing for video consultation 4. Patients with cognitive impairment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description

Our data management plan will be supervised by Rudy Scholte, head of the Amsterdam UMC data management, and will be shaped according to open science and FAIR data planning principles. For this project we will gather prospectively collected data, which we aim to make accessible for re-use in an approved (COVID-19) data repository. No already existing retrospective data repositories have been found of use for this project because of its' prospective methodological nature. The results of the VIDEOGO-trial will be published with open access.

Ethics review

Positive opinion	
Date:	10-12-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9108
Other	METC AMC : W20_514

Study results