

'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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20092

Bron

Nationaal Trial Register

Verkorte titel

VIDEOGO

Aandoening

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

Ondersteuning

Primaire sponsor: Amsterdam UMC

Overige ondersteuning: Citrienfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

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.

Ethische beoordeling

Positief advies

Datum: 10-12-2020
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9108
Ander register	METC AMC : W20_514

Resultaten