

Real-time tracking of rectal tumours during colorectal cancer surgery

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Image-guided navigation surgery allows the optimal use and full integration of pre-operative images during surgical procedure. This feasibility study investigates the potential of this new technique in surgery in rectal surgery. The hypothesis is...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25173

Bron

Nationaal Trial Register

Verkorte titel

NA

Aandoening

Open or laparoscopic surgery for rectal cancer patients

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute –Antoni van Leeuwenhoek Hospital

Overige ondersteuning: The Netherlands Cancer Institute –Antoni van Leeuwenhoek Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of this study was feasibility. Feasibility was defined as successful

completion of the whole investigational workflow resulting in continuous delivery of interpretable navigation data for rectal surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Image-guided navigation surgery allows for full utilization of pre-operative imaging during surgery. It has the potential of reducing irradical resection margins and reducing morbidity caused by damaged surrounding structures. We have developed a navigation system that can take positional changes of the tumour into account by using a tracking sensor fixed to the tumour or its surrounding tissue. This is a feasibility pilot study towards clinical implementation of this new navigation system.

Doel van het onderzoek

Image-guided navigation surgery allows the optimal use and full integration of pre-operative images during surgical procedure. This feasibility study investigates the potential of this new technique in surgery in rectal surgery.

The hypothesis is that with navigation surgeons have a better insight in the anatomy of the patient. This will improve the decision making, and can potentially also speed up the procedures. Ultimately, surgical outcome in terms of radicality and morbidity can be improved.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Use of an electromagnetic navigation system to improve insight and orientation during pelvic surgery.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

≥ 18 years

A rectal tumour within 10 cm of the anal verge (based on preoperative imaging)

A signed informed consent

Suitable for contrast enhanced CT scanning

Planned for low anterior resection (LAR) or abdominoperineal resection (APR)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Metal implants in the pelvic area

Patients for which it is impossible to do a rectal examination

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	31
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	12-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47238
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7666
CCMO	NL57251.031.16
OMON	NL-OMON47238

Resultaten