HERBERT II: external beam radiation therapy followed by high-dose rate endorectal brachytherapy (HDRBT) in elderly early rectal cancer patients not undergoing surgery: A randomized multicenter phase III study

Gepubliceerd: 11-06-2019 Laatst bijgewerkt: 15-05-2024

Clinically relevant improvement would be to observe an absolute difference of at least 25% in cCR rate.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26642

Bron
Nationaal Trial Register

Verkorte titel
HERBERT II

Aandoening

Rectal cancer

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: KWF/Alpe d'Huzes

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Complete clinical response (cCR) at 26 weeks after EBRT for the control group and at 26 weeks after the last brachytherapy fraction for the intervention group.

Toelichting onderzoek

Achtergrond van het onderzoek

A total of 106 patients will be included and receive EBRT in 13 fractions of 3 Gy to the mesorectum. Patients will then be evaluated and if there is no progressive disease they will be randomized for yes/no HDR endorectal brachytherapy boost to the primary tumor in 3 fractions of 7 Gy. Primary outcome is complete clinical response at 6 months after last radiotherapy.

Doel van het onderzoek

Clinically relevant improvement would be to observe an absolute difference of at least 25% in cCR rate.

Onderzoeksopzet

Response evaluation can be divided in 2 steps. Firstly, response will be evaluated ten weeks after end of external beam radiotherapy, to determine whether a patient can be randomized. Patients with progressive disease will not receive any further treatment. All other patients will be randomized.

The final response evaluation will be done for all randomized patients and will take place at 26 weeks after EBRT for the standard arm and at 26 weeks after the last brachytherapy fraction for the experimental arm. This evaluation will be used as timepoint for the primary endpoint.

Because endoscopic evaluation of treatment response is sometimes difficult, adjustment of the primary score is allowed. Eg: if at 6 months there is a small scar, but this does not progress for another 6-12 months, the 6 months evaluation will be scored as cCR.

Onderzoeksproduct en/of interventie

Phase III trial randomizing between EBRT (13x3 Gy) and EBRT+HDR-BT (13x3 Gy followed by

3x7 Gy brachytherapy)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adenocarcinoma of the rectum
• WHO performance status 0-3
• Frail patients unfit for surgery or refusing surgery (see §4.3)
• Tumors with a sufficient lumen to allow the positioning of the flexible, multichannel applicator
• Signed informed consent prior to start of protocol specific procedures

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Extramesorectal (e.g. iliac, lateral) pelvic lymph node involvement
• 4 or more lymph nodes > 1 cm disease on MRI (gross N2 disease)
• M1 disease
• Extension of tumour into the anal canal
• Tumor > 2/3 of the circumference
• Previous pelvic irradiation

• Prior chemotherapy
• Prior surgery for rectal cancer, except local excision > 3 months before start of EBRT
• Contra-indication for endoscopic placement of gold-markers such as coagulopathy (prothrombin time < 50% of control; partial thromboplastin time > 50 seconds) or anticoagulantia (marcoumar, sintrom or new oral anticoagulants) that cannot be stopped.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	106
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55855
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7795
CCMO	NL69261.058.19
OMON	NL-OMON55855

Resultaten