Bevacizumab modulation of telangiectasia in irradiated rectal cancer patients.

Gepubliceerd: 14-12-2011 Laatst bijgewerkt: 18-08-2022

Inhibition of VEGF with Bevacizumab may have beneficial of deleterious effects on normal rectal microvasculature long time after radiation.

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

Samenvatting

ID

NL-OMON22711

Bron
NTR

Aandoening

rectal cancer
bevacizumab
telangiectasia
radiotherapy

Ondersteuning

Primaire sponsor: NKI-AVL (Netherlands ancer Institute)
Overige ondersteuning: KWF Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary end-point of this study will be the number and size of teleangiectasia

encountered, lymph vessel morphology and immunohistochemical evaluation of inflammation and vessel maturation.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Inhibition of VEGF with bevacizumab may have beneficial or deleterious effects on normal rectal microvasculature long term after radiotherapy.

Objective:

Evaluation of the effects of the VEGF inhibitor bevacizumab on abnormal microvasculature in irradiated rectum.

Study design:

Monocenter observational study with biopsy samples of irradiated rectal mucosa at two time points; before and after minimal 3 courses and a maximum of 4 months of bevacizumab treatment. The administration of bevacizumab is clinically indicated for palliative treatment of rectal cancer recurrence and independent of participation in this study.

Study population:

Patients who have an indication for palliative bevacizumab, who have previously been treated more than 6 months earlier with pelvic radiotherapy and have an intact ano-rectal access (not an end stoma).

Inclusion criteria:

1. Patients, diagnosed with local tumor residue / recurrence or metastasis, 6 months or longer after the start of their initial pre-operative radiotherapy or chemo-radio therapy (CRT) and will now be treated with bevacizumab;

2. Rectal endoscopy is possible;

3. Aged over 18 years;

4. Written informed consent is provided.

Exclusion criteria:

1. Previous abdomino-perineal resection (APR) (no endoscopic access);

2. Anastomotic bleeding, leakage or breakdown at study enrolment;

3. Use of anticoagulants or anti aggregants.

Intervention:

Biopsies of the rectal mucosa just distal to the anastomosis will be taken prior to and Bevacizumab treatment, during rectoscopy.

Main study parameters/endpoints:

Immuno-histological assessment of micro-vascular bed, vessel structure and maturation and inflammatory cell infiltrate.

Nature and extent of the burden and risks associated with participation, group relatedness:

As part of the clinical evaluation of the effect and toxicity of the palliative treatment, patients will undergo two extra endoscopic evaluations. Biopsies will be taken of the normal rectal mucosa (in addition to any tumour). There is a small risk of local bleeding which will be helped immediately by coagulation. Assessment of the safety and toxicity profile of bevacizumab in the palliative setting is of relevance for all patients who have previously been treated with pre- or post-operative pelvic radiotherapy. This translational research is however part of a larger project to develop interventions to reduce long-term side effects of radiotherapy.

Doel van het onderzoek

Inhibition of VEGF with Bevacizumab may have beneficial of deleterious effects on normal rectal microvasculature long time after radiation.

Onderzoeksopzet

Before bevacizumab treatment and after 3 courses of bevacizumab treatment or maximum 4 months after the initial biopsy sample.

Onderzoeksproduct en/of interventie

2 sigmoidoscopies for mucosal biopsy sampling.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients, diagnosed with local tumor residue / recurrence or metastasis, 6 months or longer after the start of their initial pre-operative radiotherapy or chemo-radio therapy (CRT) and will now be treated with bevacizumab;

2. Rectal endoscopy is possible;

3. Aged over 18 years;

4. Written informed consent is provided.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous abdomino-perineal resection (APR) (no endoscopic access);

2. Anastomotic bleeding, leakage or breakdown at study enrolment;

3. Use of anticoagulants or anti aggregants.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2011
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-12-2011
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	NL3047
NTR-old	NTR3195
CCMO	NL37827.031.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A