Bevacizumab modulation of telangiectasia in irradiated rectal cancer patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22711

Source
NTR

Health condition

rectal cancer
bevacizumab
telangiectasia
radiotherapy

Sponsors and support

Primary sponsor: NKI-AVL (Netherlands ancer Institute)
Source(s) of monetary or material Support: KWF Grant

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary endpoint will be the number of complications following bevacizumab treatment and or endoscopic procedures: Rates of anastomotic leakage or breakdown, rectal ulcer or bleeding.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

2 sigmoidoscopies for mucosal biopsy sampling.

Contacts

Public
Netherlands Cancer Institute
Dept of Biometrics
S. Vanhoutvin
Amsterdam
The Netherlands
+31 (0)20 5127496
Scientific
Netherlands Cancer Institute
Dept of Biometrics
S. Vanhoutvin
Amsterdam
The Netherlands
+31 (0)20 5127496

Eligibility criteria

Inclusion criteria

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Exclusion criteria

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Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A