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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26642

Source
Nationaal Trial Register

Brief title
HERBERT II

Health condition

Rectal cancer

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: KWF/Alpe d'Huzes

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

• Acute and late toxicity (CTCAE v5)
• HRQL and functional status at 1 and 2 year
• Sustainability of response at 2 years
• Overall survival at 2 years

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

Phase III trial randomizing between EBRT (13x3 Gy) and EBRT+HDR-BT (13x3 Gy followed by 3x7 Gy brachytherapy)

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	106
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55855
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results