Tailored patient values elicitation task for rectal cancer treatment decision-making

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This research aims to assess the effect ofn completing an ACA-task on decision-making regarding short-course pre-operative radiotherapy in the treatment of rectal cancer in clinical practice.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON39040

Source
ToetsingOnline

Brief title
ABEL

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding en reserves van de

afdeling Medische Besliskunde LUMC

Intervention

Keyword: communication, treatment decision making, values elicitation

Outcome measures

Primary outcome

The proposed research aims to carry this research further, to evaluate patient and radiation oncologists* acceptance of an ACA-task incorporated as part of routine primary rectal cancer care, and to evaluate its effectiveness on:

1) the extent to which patients* values regarding treatment outcomes and tradeoffs underlying the PRT decision are explicitly communicated during the visit to the radiation oncologist;

2) correspondence between treatment choice and patient values for late side effects;

3) patients* ability to cope with late side effects at one-year follow-up.

Secondary outcome

n.a.

Study description

Background summary

Short-course pre-operative radiotherapy (PRT) in primary rectal cancer reduces local recurrence rates from 11% with total mesorectal excision (TME) surgery alone to 6% with added PRT, but strongly increases probabilities of late side effects (faecal incontinence and sexual dysfunction), without survival benefit. The guideline prescribes PRT, even though the decision to apply PRT is exemplary for a preference-sensitive decision. Those involved in developing the

guideline thus felt their preference regarding the tradeoff between benefits and side effects to be indisputable. However, clinicians have been shown to be inaccurate in predicting patient preferences. Patients are currently not made aware of the preference-sensitive nature of the tradeoff underlying PRT, and their preferences are not assessed on a routine basis. This is in contrast with findings from our research in this patient group (UL 2005-3213), in which both oncologists and patients felt that the best achievable care is a function of patient preference.
A values clarification exercise may aid patients to reflect on their values for outcomes of care. Adaptive Conjoint Analysis (ACA) is an individually-tailored, theory-based method to assess these values. In UL 2005-3213 we found the task to be feasible and valid in treated rectal cancer patients. Both patients and oncologists indicated the need to assess patient preferences in treatment decision-making and felt the ACA could support this.

Study objective

This research aims to assess the effect ofn completing an ACA-task on decision-making regarding short-course pre-operative radiotherapy in the treatment of rectal cancer in clinical practice.

Study design

This multicenter study will employ a usual care phase (N=87), followed by an intervention phase (N=87). The intervention phase will offer patients the ACA-task. The computerized ACA-task will be completed immediately prior to the consultation; it will provide immediate feedback on screen, with a copy printed out, on patients' relative preferences for five-year survival, five-year local control, faecal incontinence, and sexual dysfunction. Patients may show the copy to their oncologist if they wish.

Intervention

The intervention group will be asked to complete the ACA-task immediately prior to their visit to the radiation oncologist, in the waiting area of the radiotherapy department. It is expected that time needed to complete the task will be 15 to 20 minutes. Upon completion, a graphic summary of the relative importance scores for the four treatment outcomes is produced and printed out for the patient*s use.

Study burden and risks

This research pertains to a preference study. Patients will therefore not be exposed to risks by participating. The burden to patients for participating includes:

- reading the brochure about the study;
- receiving a phone call in which one is asked to indicate willingness or unwillingness to participate in the study;
- fill in the two questionnaires (2 x 20 minutes in usual care phase and 3 x 20 minutes in the intervention phase);
- intervention group: fill in the ACA-task (1 x 20 minutes);
- intervention phase: patient interview (1 x 20 minutes for intervention group);
- a recording on audiotape will be made of the consultation.

Patients have the right to withdraw from participation at any time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patient newly diagnosed with primary rectal cancer;
advised to undergo 5x5Gy pre-operative radiotherapy;
tumorstage T2N0-1M0 or T3N0-1M0, located 5-15 cm from the anal verge;
scheduled to undergo a low anterior resection (without permanent stoma);
and with adequate mastery of the Dutch language in speech and writing

Exclusion criteria

Distal metastases

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	174
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Approved WMO Date:	16-04-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-05-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	22-01-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-02-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	10-04-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-08-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL31747.058.10