EMBRACE Vaginal Morbidity Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cervix disorders (excl infections and inflammations)
Study type	Observational non invasive

Summary

ID

NL-OMON39692

Source
ToetsingOnline

Brief title
Vaginal Morbidity Study

Condition

- Cervix disorders (excl infections and inflammations)

Synonym
cancer of the cervix, cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medical University of Vienna, Austria Department of Radiotherapy
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cervical cancer, Radiotherapy, Sexuality and quality of life, Vaginal Morbidity

Outcome measures

Primary outcome

Vaginal changes, reported by patient and radiotherapist, and the complex interaction of the physical, dosimetric, biological, clinical and psychological factors to vaginal morbidity and the importance of these factors to sexual functioning and health related quality of life.

Secondary outcome

1. To comprehensively asses vaginal change related to radiotherapy (vaginal morbidity) over time as seen or measured at gynaecological examination.

2. To establish a vaginal dosimetry wich enables a radiotherapy dose effect relationship for physician assessed objective vaginal changes.

3. To investigate if physician recorded 'objective' vaginal changes are correlated with patient reported vaginal symptoms.

4. To examine if physician recorded 'objective' vaginal changes and/or patient reported vaginal symptoms are relevant for overall sexual functioning.

5. To evaluate the extent to which general psychological aspects (emotional sistress, relationship issues, body image, infirtility, fatigue and overall quality of life) influence sexual functioning.

6. To investigate the influence of clinically established interventions on both patient reported overall sexual functioning and physician reported vaginal changes.

Study description

Background summary

External beam radiotherapy combined with image guided brachytherapy and chemotherapy is the normal treatment for advanced stages of cervical cancer.
The ongoing EMBRACE study is an international multicenter prospective phase II study that investigates the effect of implementation of 3-dimensional image guided brachytherapy.
Image guided brachytherapy provides better treatment of the tumor, while at the same time allows better sparing of organs at risk of treatment related side effects.
Posttreatment sexual diffunction and symptoms are important factors causing long term distress for an increasing number of cervical cancer survivors.

Study objective

The aim of the vaginal morbidity sub-study is to better understand the different physical, dosimetric, biological, clinical and psychological factors and to analyse the importance of these factors for patient reported outcome on sexual functioning and health related quality of life.
Part of these questions will be answerd in the ongoing EMBRACE study but we need more detailed information.
These outcome will be relevant to introduce treatment optimisation and help guide evidence based attempts to improve sexual functioning and reduce symptoms.

Study design

The vaginal morbidity study is proposed as a sub-study of the ongoing EMBRACE study. This is an international multicenter prospective phas II study with routine follow-up time points and planned gynaecological examinations. Also patients that will not be enrolled in the EMBRACE and EMBRACE Vaginal Morbidity studie undergo the same treatment (external beam radiotherapy combined with image guided brachytherapy and chemotherapy) and have the same follow-up time points at the radiotherapy department.
For thr EMBRACE Vaginal Morbidity Study more detailed reporting of vaginal changes during clinical examination, more in depth patient reported sexuality issues and more detailed brachytherapy dose reporting are required.
In a prospective lonitudinal setting, more detailed information on physician assesed vaginal toxicity and dosimetry will be combined with patient reported information on vaginal changes, sexual function and psychological factors.
This delailed information will be documented at baseline, before start of radiotherapy, at follow-up time points of 4-6 weeks and 3,6,12 and 24 months after the end of treatment.
Assessment of:
1. Vaginal changes during planned gynaecological follow-up exam. To measure vaginal length and with standard perspex cilinders are used. Measurements at

baseline, 4-6 weeks and 3,6,12 and 24 months after completion of radiotherapy.
2. 16 extra questions, to measure the effect on sexual function, will be added to the quality of life questionaire.
3. All patients are advised to use vaginal dilators after radiotherapy to reduce side effects. Patients in this studie are asked about the frequency, size and compliance of dilation.
4. To correlate vaginal morbidity to the vaginal dose, extra dosepoints will be added in the radiotherapy treatmentplans (external beam and brachytherapy).

Study burden and risks

Burden and risk of the study is verry low.
Existing EMBRACE quality of life questionnaires have additional items to asses issues related to sexuality. These questionnaires have the same timepoints as the existing routine follow-up points and take not more than 15- 20 minutes.
During routine clinical examination(at baseline, before start of radiotherapy, at follow-up time points of 4-6 weeks and 3,6,12 and 24 months after the end of treatment) radiation induced vaginal changes (length, with and mucosal aspects) are measured . These measurements will consume just a minimal extra time during the regular follow-up.

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

- Cancer of the uterine cervix suitable for curative treatment with definitive radio-(chemo)therapy including 3D image guided Brachytherapy.
- Positive biopsy showing squamous-cell carcinoma, adenocarcinoma or adeno-squamous cell carcinoma of the uterine cervix.
- Staging according to FIGO and TNM guidelines
- FIGO stage IB1-IIIB, without vaginal extension (stage IIA and IIIA not allowed)
- Para-aortic metastatic nodes below L1-L2 are allowed
- Patient informed concent
- Ability to read, understand and fill in questionaires on quality of life and sexuality

Exclusion criteria

- Other primairy malignancies exept carcinoma in situ of the cervix and basal cell carcinoma of the skin.
- Metastatic disease beyond para-aortic region (L1-L2)
- Vaginal extension of primary tumor.
- Pre-existent major vaginal morbidity.
- Previous pelvic or abdominal radiotherapy
- Combination of preoperative radiotherapy with surgery
- Patients receiving BrachyTherapy only.
- Patients receiing ExternalBeamRadioTherapy only.
- Patients receiving neoadjuvant chemotherapy
- Cotraindications to BrachyTherapy
- Active infection or severe medical condition endagering treatment delivery

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2013
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	07-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-01-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL41941.041.12