REQUITE: Validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality-of-life in cancer survivors

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Primary ObjectiveTo establish a prospective cohort of patients undergoing radiotherapy for breast, prostate or lung cancers following local regimens and collecting standardised radiotherapy toxicity data, non genetic risk factor data and samples for...

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

Summary

ID

NL-OMON42419

Source
ToetsingOnline

Brief title
REQUITE

Condition

- Prostatic disorders (excl infections and inflammations)
- Respiratory tract neoplasms

Synonym
malignant prostate tumour or lung tumour, prostate cancer or lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic
Source(s) of monetary or material Support: door de Europese Unie (7th Framework Programme of the European Commission (Grant number 601826)

Intervention

Keyword: cancer, predictive models, toxicity, treatment

Outcome measures

Primary outcome

* Prostate: Rectal bleeding at 24 months following start of radiotherapy

* Dyspnea/ breathlessness at 12 months following start of radiotherapy (lung)

Secondary outcome

* Other toxicity endpoints including but not limited to: rectal incontinence,

urinary toxicity and erectile dysfunction (prostate), dysphagia and

oesophagitis (lung)

* Quality of Life (QoL)

* Maximum grade of toxicity during follow-up period

Study description

Background summary

With increasing life expectancies and improvements in diagnosis and treatment, the number of cancer patients and survivors is expected to continue to rise. As the illness increasingly becomes a chronic disease, cancer patients* quality-of-life needs to be addressed in a systematic manner in order to enhance their participation in society, including the workplace. Approximately half of all cancer patients receive radiotherapy as part of their cancer treatment. The dose of radiation given is limited because of a risk of damaging the normal tissues and organs that surround the tumour. Patients vary in how they react to radiation. About 5% of patients (5 out of every 100) are sensitive and at risk of having side effects. In recent years predictive models

have been developed that attempt to identify before the start of treatment patients at risk of long-term side-effects. These emerging models require systematic validation in a multi-centre collaborative setting. There are an increasing number of datasets available for validation but they are variable in terms of the data collected.
This multi-centre observational study will be the largest study of its kind collecting blood samples and standardised data longitudinally from 5,300 cancer patients. It will enable validation of models that predict a patient*s risk of developing long-term side-effects following radiotherapy. It will be a unique (eventually widely accessible) resource for studying the relationships between side-effect endpoints and between side-effects and quality-of-life. It is known that genetics influence a patient*s risk of developing side-effects and a number of assays/approaches have been explored to assess a patient*s sensitivity to radiation. This prospective observational study will allow for the validation of the most promising biomarkers/approaches.

Study objective

Primary Objective

To establish a prospective cohort of patients undergoing radiotherapy for breast, prostate or lung cancers following local regimens and collecting standardised radiotherapy toxicity data, non genetic risk factor data and samples for biomarker assays for the study of determinants of radiotherapy side-effects.

Secondary Objective

To establish a comprehensive centralised database and sample collection as a resource for the prospective evaluation and validation of clinical models incorporating biomarker data to identify before treatment those cancer patients who are at risk of developing long term side-effects from radiotherapy.

Study design

This is an international observational cohort study. Eligible patients will have cancer of the breast (invasive or in situ), prostate or lung and be due to receive radical radiotherapy or adjuvant radiotherapy after breast conserving surgery or prostatectomy. Patients will be recruited from participating outpatient oncology clinics via cancer centres in multiple countries including Belgium, France, Germany, Italy, Spain, The Netherlands, UK and USA. Data on radiotherapy toxicity, non-genetic risk factors (e.g. dosimetry, chemotherapy use, age, diabetes, smoking history, co-morbidity) and quality of life will be collected at specified time points prospectively. Pre-treatment blood samples will be collected from all patients for downstream analyses. Patients will be required to have understood information about the study and given written

informed consent.

Study burden and risks

REQUITE is an observational study and the treatment will not change by taking part in this study. Patients will be asked to complete some questionnaires and to give a blood sample. Potential harms of taking blood are a large bruise (haematoma) or extremely rarely impairment of nerves. There will be no direct benefit for the patient.

Contacts

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MAASTRO clinic

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Confirmed diagnosis of the specified tumour types, for lung cancer confirmation either by histology or based on radiological findings
* Patients suitable for radical radiotherapy or brachytherapy for prostate cancer; including post-prostatectomy patients
* Patients suitable for radical radiotherapy, sequential or concurrent chemoradiotherapy or stereotactic body radiation therapy for lung cancer
* No other malignancy in the last 5 years prior to treatment for the specified tumour types except basal cell or squamous cell carcinoma of the skin
* No evidence of distant metastases
* Patients able to provide a venous blood sample
* Willingness and ability to comply with scheduled visits, treatment plans and available for follow up within country of origin
* Greater than 18 years of age; no upper age limit
* The capacity to understand the patient information sheet and the ability to provide written informed consent

Exclusion criteria

* Patients with metastatic disease
* Prior irradiation at the same site
* Planned use of protons
* High Intensity Focal Ultrasound (HIFU)
* Mental disability or patient otherwise unable to give informed consent and/or complete patient questionnaires
* Limited life expectancy due to co-morbidity
Pregnant patients
* Patients with known HIV infection/infectious hepatitis

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	18-01-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-08-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ISRCTN	ISRCTN98496463
CCMO	NL54472.068.15