Diffusion changes due to hyperthermia treatment for locally advanced cervical cancer

Published: 12-12-2017
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To establish the changes in tumour diffusion hyperthermia induces in humans.

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

Summary

ID

NL-OMON44183

Source
ToetsingOnline

Brief title
HT-diffusion-1

Condition

- Cervix disorders (excl infections and inflammations)

Synonym
cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Cervical cancer, Diffusion, Hyperthermia, Perfusion

Outcome measures

Primary outcome

Diffusion changes in the tumour.

Secondary outcome

Perfusion changes in the tumour.

Study description

Background summary

Currently used clinical treatment schedules are based on biological knowledge of the late 1970s while recent discoveries have been made that suggest other schedules may improve treatment efficacy. The improved understanding on the hyperthermia interaction on tumour diffusion might lead to optimized scheduling of the hyperthermia fractions with the radiotherapy fractions during the whole radiotherapy + hyperthermia treatment series.

Study objective

To establish the changes in tumour diffusion hyperthermia induces in humans.

Study design

This trial is a prospective longitudinal within-subject study. Patients will already be in the MR-scanner for the standard hyperthermia treatment. In two of the five treatments, they will receive 3 extra diffusion weighted imaging (DWI) scans.

Study burden and risks

No adverse of DWI-MRI scans are known. Patients will already be in an MR-scanner as part of their standard treatment. Study burden consists of 16 minutes of extra time in the scanner.

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

Patients with advanced cervical cancer who will receive MRI-guided hyperthermia as part of standard care. In addition, patients need to have a macroscopic tumour at the first hyperthermia treatment.

Exclusion criteria

Claustrophobia

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-12-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL62907.078.17