

# Diffusion changes due to hyperthermia treatment for locally advanced cervical cancer

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Cervix disorders (excl infections and inflammations)
<b>Study type</b>	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

### **Public**

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### **Scientific**

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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

CCMO

### ID

NL62907.078.17