MRHeatflow-Study: an observational study of changes in pelvic circulation during radiotherapy with or without hyperthermia in patients with cancer of the small pelvis

Published: 22-05-2023
Last updated: 30-11-2024

Investigation of pelvic blood circulation by MRI in women with a gynaecological cancer who will have curative radiotherapy with or without weekly HT for inoperable pelvic tumours.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational non invasive

Summary

ID

NL-OMON54245

Source
ToetsingOnline

Brief title
MRHeatflow study

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
gynaecological cancer, pelvic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: gynaecological cancer, hyperthermia, MRI, radiotherapy

Outcome measures

Primary outcome

The primary end-point is to show feasibility of perfusion MRI by determining significant changes in blood circulation in HT and RT patients. Furthermore, several secondary end-points aim at using the data for hypothesis generating and retrieving the essential preliminary data to allow for designing more in depth studies into using perfusion MRI as biomarker for HT efficacy.

Secondary outcome

See above.

Study description

Background summary

HT has different effects on cells and tissue that may explain the effects. At temperatures >= 39-40°C, HT gives vasodilation. On the one hand, increased circulation leads to an increased oxygen supply to the tumor, making the tumor more sensitive to radiation (= increased tumor control). On the other hand, increased circulation can increase cooling of the tumor, which could reduce the effect on tumor cells. Blood flow to the tumor and surrounding tissue can be measured by MRI. In this study we wish to investigate in patients the effect of radiation with or without HT on the blood flow in tumor and in healthy tissues, bfore, during the course of radiation and after radiotherapy.

Study objective

Investigation of pelvic blood circulation by MRI in women with a gynaecological

cancer who will have curative radiotherapy with or without weekly HT for inoperable pelvic tumours.

Study design

A non-randomized prospective observational study in patients receiving daily RT with weekly HT compared to patients who do not receive HT (who typically will receive RT plus weekly chemotherapy). Patients will receive 3 standard MRIs at several points before, after 3 weeks into treatment, and 3 months after treatment. Each standard MRI takes about 20 min.

For study purposes:
- All patients will receive extra MRI scans during the standard MRI of 20 minutes, which include Dotorem contrast agent injection.
- between 10 to 30 patients who, as standard of care, have RT plus hyperthermia will have 3 extra MRI scan moments (repeated baseline, a scan right after the first and third HT session) of 40 minutes, of which 1 includes a Dotarem contrast agent injection.

Study burden and risks

An MRI typically takes 20 min, adding administration of i.v. Gd-contrast, DCE (~10 min) and intravoxel incoherent motion diffusion weighted MRI (IVIM-DWI) (~10 min), will prolong the investigation to max. 40 min. Administration of i.v. Gd-contrast is associated with a small risk of an allergic reaction, and with extravasation and haematoma (erroneous administration of the i.v. contrast) causing temporary discomfort.

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

All adult patients (18 years or older) with pelvic cancer who are possibly eligible for curative radiotherapy with or without hyperthermia

- 18 years or older
- histologically confirmed primary pelvic tumour,
- possibly eligible for primary radiotherapy (with or without chemotherapy and/or hyperthermia)

- able to understand and read Dutch or English,
- written informed consent (Dutch or English)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- all who do not comply to the inclusion criteria
- those with a contra-indication for MRI (i.e. MRI incompatible metal implants, pacemaker, severe claustrophobia)
- those with a contra-indication for MRI-contrast agent (i.e. known allergic reaction, poor functioning of the kidneys eGFR<30 mL·min*1·1.73 m*2)
- pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2024
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	22-05-2023
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO

Date:	22-05-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	25-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL77270.018.21