MRI BASED HYPERTHERMIA PLANNING An Investigation in Women with Cervical Cancer

Published: 10-01-2013
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Determination of dielectric properties by MRI in women with cervical cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON37115

Source
ToetsingOnline

Brief title
MRI BASED IMPROVED HYPERTHERMIA

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cancer of the uterine cervix

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF-project UVA 2010-4660

Intervention

Keyword: MRI hyperthermia radiotherapy cervical cancer

Outcome measures

Primary outcome

Measurement of variation in pelvic anatomy in patients with cervical cancer by MRI, and the variation in corresponding distribution (and inaccuracy of measurement) of dieletric properties, and the assessment of these variations on subsequent HT treatment planning (in silico). (Note: HT in patients is not a part of this study).

Secondary outcome

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Study description

Background summary

Hyperthermia (HT) in oncology is defined as heating of the tumour to 42-43 oC during 1 tot 1.5 hours. HT is one of the most potent sensitizers of radiotherapy (RT) against cancer. A randomized study from the AMC and ErasmusMC has shown that HT improves survival of women with inoperable cervical cancer from 40% after RT-alone to 60% after RT+HT. However, optimal delivery and effect of HT depends of the highly variable dielectric and thermal properties of tumour and normal tissue. Treatment planning can yield optimal HT delivery when the dielectric tissue properties are known. Magnetic resonance imaging (MRI) can help to measure these dielectric properties.

Study objective

Determination of dielectric properties by MRI in women with cervical cancer.

Study design

Observational study.

Intervention: Standard MRI with scopolamine (10 mg supp.) and intravenous contrast in patients with cervical cancer (40 minutes). The study-protocol is extended with extra measurements, so-called B1 mapping by spin-echo sequence using a 3 Tesla MRI. This requires extra time (20 minutes).

Study burden and risks

- Time: MRI sampling: ~60 minutes
- Pre-medication: Scopolamine 10 mg supp.
- Intravenous gadolinium contrast: One time intravenous administrations of standard gadolinium contrast (Gadovist®). Gadovist® is a safe contrast medium, although allergic reactions have been reported in 0.07% [Dilman, 2007]. Dosage = body weight * 0.1 ml (1 µmol/l; usually 6 to 8 ml per patient). The i.v. device will stay in situ until the end of the MRI-scanning to allow in case of emergency, a rapid i.v. anti-allergic drug.

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

20 adult patients with newly diagnosed cervical cancer undergoing tumour staging by MRI, and

Exclusion criteria

• Inability of the patient to provide informed consent or legally incompetent/incapacitated to do so,
• Presence of metal in the body (e.g. osteosynthetic material, pacemaker, artificial cardiac valves, brain clips),
• Claustrophobia
• Pregnancy

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):	23-08-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	10-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Not approved	
Date:	07-03-2014
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	NL42126.018.12