Intra tumoral Oxygenation; A Predictor for Treatment outcome in Cervical Cancer.

Published: 12-10-2006
Last updated: 20-05-2024

To study tumor oxygenation in woman with cervical carcinomaPrimarily: To study the feasibility of measuring tissue pO2 with the FDA approved Eppendorf needle electrode and to correlate these results with promising new non-invasive methods to measure...

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON29843

Source
ToetsingOnline

Brief title
Tumor oxygenation in cervical cancer

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cervical cancer, Hypoxia markers, MRI, Tumor oxygenation

Outcome measures

Primary outcome

1. feasibility of techniques

2. Oxygenation parameters (appendix 1:

P50 value

HP 2.5

HP 5.0

HP 10.0

Ktrans (exchange rate)

Ve (extravascular volume)

OER (Oxygen Extraction Ratio)

Gene expression profiles

HIF-1*

CA-9

Lactate

PAI-1

osteopontin

D-dimer

VEGF

bFGF

TGF-*

TNF-*

IL-8

Local control

Failure free survival

Overall survival

Acute toxicity

Late toxicity

Secondary outcome

Local control

Failure free survival

Overall survival

Acute toxicity

Late toxicity

Study description

Background summary

Radiotherapy is the mainstay of treatment for locally advanced (FIGO stage II * IV) or bulky FIGO stage IB tumors and for medically inoperable patients.
In recent years, several randomized prospective trials have shown that combination treatment with chemotherapy (chemoradiation) or with regional hyperthermia (thermoradiation) has greatly improved tumor control and survival Combined modality treatment is now regarded as the standard treatment for locally advanced cervical cancer. Hypoxia and anaemia are considered some of the key contributors to radioresistance and final outcome of initiated cancer therapy. It is well known that hypoxia induces radioresistance. Results from a recently published small-scale study indicate hyperthermia to effect both tumor oxygenation as well as treatment outcome.
Invasive measurement of the partial pressure of oxygen by polarography using the Eppendorf needle electrode is the most frequently applied method. It is still considered as the *gold standard* for measurements of tissue PO2.

Study objective

To study tumor oxygenation in woman with cervical carcinoma

Primarily: To study the feasibility of measuring tissue pO2 with the FDA approved Eppendorf needle electrode and to correlate these results with promising new non-invasive methods to measure hypoxia, using dynamic contrast enhancement MRI and functional Blood Oxygenation Level Dependent MRI.
Eventually: We want to start a larger study with a more specific patient population that receives combined modality treatment to assess the effect of additional hyperthermia on:
* tumor hypoxia.
Specifically to determine the relationship between:
* tumor hypoxia measured by Eppendorf polarographic electrode system,
* tumor hypoxia measured with non-invasive techniques,
* expression of a selection of (potential) endogenous hypoxia markers and cytokines in blood plasma.
and to correlate that relationship with:
* thermal dose,
* response to given therapy,
* local control,
* development of distant metastases,
* development of normal tissue toxicity,
in order to develop a non-invasive, prognostic method that is uniformly applicable and will help to identify patients with poor prognosis who will benefit most from additional hyperthermia treatment. In addition, optimization of combined modality treatments involving hyperthermia might be accomplished by adjusting temperature and treatment sequence in relation to oxygenation status of the tumor to improve treatment response.

Study design

Pilot-study.
After given informed consent, tumor oxygenation will be measured in 10 patients with cervix cancer, using a minimally invasive polarographic needle electrode (Eppendorf pO2 histograph, Eppendorf, Hamburg, Germany). The first oxygenation measurement will take place during the routine examination under anesthesia. The second Eppendorf measurement will be done in week one of radiotherapy. If patients receive hyperthermia treatment the second oxygenation assessment will take place 24 hours after the first hyperthermia treatment. A non-invasive method of tumor hypoxia measurement will be used with the methodology of dynamic contrast enhanced MRI and BOLD fMRI, before treatment, immediately after the diagnostic scan. During routine blood analysis extra blood samples (10 ml) are taken on a weekly basis for a period of 6 weeks.

Study burden and risks

Extra MRI-scan will be performed

During routine examination under anesthesia a tumor oxygenation assessment will take place, but this procedure is asociated with a minimal risk of bleeding or pain.
The second oxygenation measurement requires an addiotional vaginal examination
During routine blood analysis extra blood samples (10 ml) are taken on a weekly basis for a period of 6 weeks.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1100 DD, Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1100 DD, Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Histologically proven carcinoma of the uterine cervix
(primary tumor: FIGO stages I-IV, or local recurrence),
2. Age >18 years,
3. Written informed consent.

Exclusion criteria

1. Patients without a tumor accessible by vaginal inspection,
2. Patients with severe vaginal blood loss,
3. Patients with psychosocial or somatic disorders in the medical history limiting the possibilities for adequate follow-up,
4. Patients with a pacemaker or other metal objects not suitable for MRI
5. Patients unable to receive propofol anesthesia

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2006
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL13280.018.06