Effects of irradiation on hypoxia and proliferation in cervical cancer and their potential predictive value; a pilot study

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The objective is to determine if, and if so to what extend, there is a change in expressionpattern for hypoxic en proliferative markers.

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

Summary

ID

NL-OMON31899

Source
ToetsingOnline

Brief title
Effects of irradiation on hypoxia and proliferation in cervical cancer

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Cervical cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cervical cancer, hypoxia, irradiation, proliferation

Outcome measures

Primary outcome

This study will look primary at het changes in expression of hypoxia en

proliferation markers early in the treatmentcourse of cervical cancer.

Secondary outcome

Not applicable

Study description

Background summary

Tumour hypoxia is an important variable in the treatment outcome (i.e. radiotherapie or systemic treatment) of cervical cancer. Hypoxia is related to al less favourable prognosis. Proliferation is a second important variable. Both variables are known prognostic factors in cervical cancer. Both radiotherapy and chemotherapy can influence the hypoxic en proliferative status of a tumour. Experimental studies have shown a reduction in expression of hypoxic markers (pimonidazole as exogeneous marker) and proliferation markers with a single fraction dose of 20 Gy. Next to the reduction in proliferation was an increase in apoptosis visible. An alterered expression pattern of hypoxia and proliferation may lead to a better predictive value than the expression pattern prior to treatment. To our knowledge this is the first clinical study to investigat this in cervical cancer.

Study objective

The objective is to determine if, and if so to what extend, there is a change in expressionpattern for hypoxic en proliferative markers.

Study design

Patients who are treated with radiotherapy or radiotherapy combined with chemotherapy or hyperthermia will have a biopsy after pimonidazole administation after the fifth and tenth radiotherapyfraction. The biopsy will

take place at the outpatient gynaecology department.

Study burden and risks

Pimonidazole will be administered intravenously to patients after te fifth and tenth radiotherapy fraction. Pimonidazole is a validates marker for hypoxia and widely used in clinical research. No serious side effects are known with the administered dosage of maximal 1000 mg. Possible side effects during infusion are a slight flush or unwellbeing. After the administration of pimonadazole a biopsy will be taken of the tumour. This will take place at the outpatient gyaecology department if needed with the use of a local anesthetic.

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

Histologically proven cervical cancer
Treatment must be radiotherapy or radiotherapy combined with chemotherapy/hyperthermia
Mentally capable of understanding the study
Age > 18
Participated in study 2006/172

Exclusion criteria

Bleedingdisorders
pregnancy
former treatment for this tumour
not capable of understanding the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL23723.091.08