Hypoxia, proliferation and its co-localization in cervical cancer

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1. To what extend does hypoxia occur in cervical cancer and what is the intra- and intertumor heterogeneity?2. To what extend does proliferation occur in cervical cancer and what is the intra- and intertumor heterogeneity?3. Does co-localization of...

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

Summary

ID

NL-OMON30128

Source
ToetsingOnline

Brief title
Hypoxia, proliferation and its co-localization in cervical cancer

Condition

- Reproductive neoplasms male 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: KWF kankerbestrijding

Intervention

Keyword: cervical cancer, Hypoxia, Proliferation

Outcome measures

Primary outcome

1. To what extend does hypoxia occur in cervical cancer and what is the intra- and intertumor heterogeneity?

2. To what extend does proliferation occur in cervical cancer and what is the intra- and intertumor heterogeneity?

3. Does co-localization of hypoxia and proliferation markers occur in cervical cancer and to what extend?

Secondary outcome

4. Is there a correlation between hypoxia, proliferation and other tumor variables like stage, grade, metastases, tumor size, and tumor growth pattern?

Study description

Background summary

Little is known about the co-localization of hypoxia and proliferation in cervical cancer. In the future it may be possible that hypoxia and/or proliferation markers will be used to differentiate between treatment modalities for cervical cancer. Tumor oxygenation is an important variable in the efficacy of radiotherapy. The response of human cells to ionizing radiation is strongly dependent on the availability of oxygen. Different studies have shown that tumor proliferation and hypoxia are independent predictors of treatment results in cervical cancer. Exogenous and endogenous hypoxia and proliferation markers (Ca 9, Ki-67) are available for study. Pimonidazole is a nitroimidazole and a proven valid marker for hypoxia

Study objective

1. To what extend does hypoxia occur in cervical cancer and what is the intra-

and intertumor heterogeneity?
2. To what extend does proliferation occur in cervical cancer and what is the intra- and intertumor heterogeneity?
3. Does co-localization of hypoxia and proliferation markers occur in cervical cancer and to what extend?

Study design

Analysis of co-localization of hypoxia and proliferation in cervical cancer, using pimonidazole as hypoxia marker and Ki-67 as proliferation marker.
- Administration of an hypoxia marker before the examination under anaesthesia
- Examination under anaesthesia with several biopsies
- Further processing of the biopsy at the department of pathology
- Immunohistochemical staining of tumor biopsies
- Quantifying Pimonidazole and Ki-67 staining
- Correlation with other tumor parameters
- Correlation with clinical parameters (stage, grade, lymphnode status (in case of surgery), LVSI, etc)

Study burden and risks

Patients will receive an injection with Pimonidazole before the examination under anaethesia (Iv access already necessary for the anaesthesia. There will be extra biopsies taken from the cervix.

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

Proven cervical cancer or a high suspicion on cervical cancer

Exclusion criteria

Unable to understand and comprehend the study.
Treated for this tumor before

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	25
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	NL13570.091.06