The immunological aspects of conventional therapies for the treatment of cervical cancer. An exploratory study to monitor the immunological effects of radiotherapies in cervical cancer patients

Published: 07-10-2011
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To monitor the effects of radiotherapy alone, chemoradiation and radiotherapy combined with hyperthermia on the immune response and different T cell subsets over time in patients 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-OMON35864

Source
ToetsingOnline

Brief title
The immunological effects of radiotherapy

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cancer of the cervix, cervical cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cervical cancer, immunomonitoring, radiotherapy

Outcome measures

Primary outcome

The time-related immuneresponse during and after treatment with radiotherapy in

cervical cancer patients. T cell phenotypic changes and T cell-related immune

cell functional changes will be investigated.

Secondary outcome

N/A

Study description

Background summary

Radiotherapy is an important treatment for cervical cancer which can be used in both a curative and palliative setting. Although radiotherapy is known to negatively affect lymphoid cells, accumulating evidence indicates that radiotherapy may also modify the tumour environment and stimulate an antitumoural immune response. These immunomodulatory properties could predict collaboration between cancer immunotherapy and radiotherapy in future. However, the effect of radiotherapy on the general and the HPV16 E6 and E7-specific immune responses is currently not well evaluated. Therefore the aim of this exploratory study is to investigate the general and HPV-specific T cell responses before, during and after radiotherapy.
This study is a part of a combined LUMC / CHDR clinical immunopharmacology research line.

Study objective

To monitor the effects of radiotherapy alone, chemoradiation and radiotherapy combined with hyperthermia on the immune response and different T cell subsets

over time in patients with cervical cancer.

Study design

Open, observational, exploratory study

Study burden and risks

All participating patients will be treated with standard radiotherapy, exactly the same as when they wouldn't participate.
Only some additional blood sampling will take place for study purposes. Blood sampling will take place during rregular hospital visits.

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

- Patients should be at least 18 years of age;
- Patients should be able and willing to provide informed consent;
- Patients should have the clinical diagnosis of cervical cancer;
- Patients are scheduled for:
1. Primary external beam radiotherapy (EBRT) with intra-uterine brachytherapy (BT);
2. Primary EBRT with intra-uterine brachytherapy (BT) and concurrent chemotherapy (Cisplatin);
3. Primary EBRT with intra-uterine brachytherapy (BT) and combined with hyperthermia;
4. Adjuvant, post-operative external beam radiotherapy (EBRT);
5. Adjuvant, post-operative EBRT with concurrent chemotherapy (Cisplatin).

Exclusion criteria

- Any medical condition that may interfere with the study objectives;
- Positive test result for HIV or Hepatitis B;
- Any other active malignancy than cervical cancer.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-05-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	05-06-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL36829.058.11