Biomarker evaluation in advanced stage cervical cancer by an international working group. Tumor Stages (1B1-4).

Published: 03-06-2014
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Assess dominant mutations and activation pathways in cervical cancers predictive to standard treatment response.

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

Summary

ID

NL-OMON41533

Source
ToetsingOnline

Brief title
BIO-RAIDs

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Cervical cancer, cervical carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Institut Curie
Source(s) of monetary or material Support: EU

Intervention

Keyword: Advanced, Biomarkers, Cervical cancer, Evaluation

Outcome measures

Primary outcome

• Frequency of dominant genetic or protein alterations

• Non response to primary treatment at 6 months as determined by:

I Pathology

II Cross sectional imaging by MRI (pelvic mass) and CT

scan (extrapelvic).

Secondary outcome

• Determination of PFS at 18 months in correlation with dominant genetic or

protein alterations

• Descriptive analysis of standard treatment modalities applied in

participating European countries

• Descriptive analysis of grade 3&4 treatment-associated side effects and

toxicities

• Descriptive analysis of molecular alterations frequency according to

geographic location.

Study description

Background summary

Cervical cancer is the second most common cause of cancer death in women worldwide. Every year 270,000 women die from cervical cancer and another 500,000 are newly diagnosed.
Recent progress towards cervical cancer prevention was documented in a seminal

study using preventive anti HPV vaccines. Despite the enthusiasm with the initial results of anti human papillomavirus (HPV) vaccination, it is generally accepted that cervical cancer screening will have to continue, in particular because the population most at risk will not have been vaccinated. Vaccination is expected to impact incidence rates in more than 20 years from now when the first vaccinated adolescents will have reached the age of developing cervical cancer. Prior to that, patients who develop cervical cancer will not have been vaccinated. We should also consider that the population *at risk* may not seek vaccination for a variety of reasons. There is therefore a need today for the improvement of CC medical practices in terms of diagnosis and treatment. Furthermore, cervical cancer primarily affects younger women, with the majority of cases appearing between the ages of 35 and 50, when many women are actively involved in their career or caring for their families. The burden of cervical cancer is particularly high in the new member states. The highest annual world-standardized mortality rates are currently reported in Romania, Serbia and Lithuania (11.4 - 9.2 and 10.0 /100 000, respectively) and the lowest rates in Finland (1.1 /100 000) while average mortality rates in France, Germany and The Netherlands are reported at 2.2- 2 and 1.7 /100 000, respectively. Governmental authorities, parliamentary representatives should be aware that the disparity of this public health problem in the east of the EU requires special attention.

Study objective

Assess dominant mutations and activation pathways in cervical cancers predictive to standard treatment response.

Study design

Prospective Multicentric European trial with tumour biopsies, and blood collection for molecular analysis at predetermined time points.

Study burden and risks

Patients will have 1-5 time a biopsy and they will also give additional bloodsamples (7x). This seems to be a mild load.
Biopsies of the cervix may cause mild vaginal bleeding, this usually stops spontaneously. In some rare cases vaginal bleeding is severe and lead to a short hospital stay for observation. Furthermore, there are no risks / side effects to be expected.

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

1)No prior treatment for cervical cancer.
2)FIGO Stage IB1 to IVB; all histological subtypes (excluding neuro-endocrine type).
3)Pelvic MRI available or planned before the start of treatment if FIGO >= IB2, and optional for IB1 stage
4)Possibility to communicate imaging data by CD ROM (format DICOM 3.0 or more).
5)Disease amenable to biopsy (3 tumour samples are mandatory prior to treatment).
6)Age >= 18 years.
7)ECOG 0-2.
8)Life expectancy > 6 months.
9)Patient eligible for standard treatment
10) Patient having health care insurance.
11) Informed and signed consent by patient.

Exclusion criteria

1)Patient enrolled in a clinical trial involving an investigative new agent.
2)Co morbidity, preventing patient to tolerate the proposed standard treatment.
3)Past history of invasive cancer over the 5 years preceding entry in the present trial (except basal cell carcinoma and carcinoma in situ of the cervix).
4)Impossibility to carry out evaluation by MRI (patient claustrophobic, pacemaker, metallic implant, non availability, other), if FIGO >= IB2.
5)Patient deprived from ability to decide on her own.
6)Patient unable to have a regular follow up for geographical, social or psychological reasons.
7)Pregnancy or patient old enough to procreate and not using effective contraceptive method.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	03-06-2014
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	26-06-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-08-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-10-2015
Application type:	Amendment
Review commission:	METC NedMec

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	NL43701.031.13