Tumoroids in cervical cancer: tumor cultures to test sensitivity for treatment and to compare with clinical outcomes after neo-adjuvant therapy.

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Primary objectives: To optimize ex vivo testing procedures for cervical cancer patients derived tumor tissue tumoroids culturing from tissue from the primary tumor.To evaluate the success rate of ex vivo drug sensitivity testing for cervical cancer...

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

Summary

ID

NL-OMON54137

Source
ToetsingOnline

Brief title
Tumoroids in cervical cancer

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: Vitroscan/Ocello BV

Intervention

Keyword: cervical cancer, ex vivo testing, neo-adjuvant chemotherapy, tumoroids

Outcome measures

Primary outcome

Optimizing procedures for ex-vivo tumor testing for cervical cancer

Evaluation of success rates of ex vivo drug sensitivity testing for cervical cancer patients eligible for NACT

explorative testing of ex vivo immune drug sensitivity for cervical cancer.

identification of tumor characteristics/ biomarkers/molecular markers that predict response to multiple neo adjuvant chemotherapy options.

Secondary outcome

To evaluate the correlation between ex vivo drug sensitivity using tumor tissue derived before chemotherapy and the clinical response in women with cervical cancer who wish to preserve fertility and are treated with neo-adjuvant chemotherapy in order to enable less radical surgery.

Study description

Background summary

Neo-adjuvant chemotherapy (NACT), which involves administration of chemotherapy prior to surgical therapy, has become a valid option in cervical cancer, especially in patients with a desire to become pregnant. The aim of neo-adjuvant chemotherapy is 2-fold: both down-staging and down-sizing which would result in more favourable outcome after less radical surgery in case of fertility sparing surgery (FSS). However, the response to NACT is uncertain: although most patients tend to respond, in 15-30% of cases no effect is achieved after NACT. In cases without response to NACT other, possible

effective, treatment is delayed. Until now there is no diagnostic test to predict responsiveness to NACT in gynaecological cancer in general and cervical cancer in specific. This protocol evaluates the feasibility to establish ex vivo testing of tumor tissue from patients who have cervical cancer and will be submitted to chemotherapy before FSS.

Study objective

Primary objectives: To optimize ex vivo testing procedures for cervical cancer patients derived tumor tissue tumoroids culturing from tissue from the primary tumor.
To evaluate the success rate of ex vivo drug sensitivity testing for cervical cancer patients eligible for NACT
To identify tumor characteristics/ biomarkers/molecular markers that predict response to multiple neo adjuvant chemotherapy options.
To evaluate drug sensitivity to novel (immune) drugs.
Secondary objective: To evaluate the correlation between ex vivo drug sensitivity using tumor tissue derived before chemotherapy and the clinical response in women with cervical cancer who wish to preserve fertility and are treated with neo-adjuvant chemotherapy in order to enable less radical surgery.

Study design

The study is a prospective cohort pilot study which will be executed at the gynecological department in two hospitals (LUMC/AVL) and the department of Pathology (LUMC). Patients will be eligible for this study if they have cervical cancer (tumor size 2<=4cm) and have a fertility wish. To evaluate if women are eligible for neo-adjuvant chemotherapy in order to downsize the tumor size and to allow less radical fertility sparing surgery afterwards, women will undergo a pelvic lymphadenectomy to exclude metastases. A biopsy from the tumor will be taken during the pelvic lymphadenectomy.

Study burden and risks

Patients who have cervical cancer (measuring 2<=4 cm) and have a fertility wish will need one extra biopsy of the tumor during the pelvic lymphadenectomy.

This biopsy will be performed under general anesthesia.
Only small risks are expected, such as local infection or local bleeding.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients are eligible for this study in case they meet the following inclusion criteria:

• Patients must have histologically confirmed invasive cervical cancer with adenocarcinoma, adenosquamous or squamous histology and FIGO 2018 IB2 measuring >2cm to <=4cm by magnetic radiological imaging (MRI). Lymphovascular space invasion (LVSI) is allowed.
• Patients must be >=18 years of age, and < 40 years of age
• Patients must be premenopausal and wish to preserve fertility
• At time of registration, patient may not have had any prior therapy to treat their cancer lesion, patients with diagnostic cone or LEEP are allowed
• Eastern Cooperative Group (ECOG) performance status <= 2 (Karnofsky >=60%, see Appendix C).
No evidence of active uncontrolled infection (patients on antibiotics are eligible).
Patient must have disease that is measurable per RECIST 1.1.
• Ability to understand and willing to sign a written informed consent document.
• Patients must agree to use effective contraceptive methods prior to study entry, during study participation, and for at least one year after the FSS

procedure.

Exclusion criteria

Exclusion criteria for this study:
• Patients who have had chemotherapy or radiotherapy or surgery for their cancer. Patients with diagnostic cone or LEEP are allowed
• Patients who are receiving any other investigational agents.
• Patients with other cancers requiring ongoing treatment. Patients with malignancies unrelated to their cervical cancer can be included if they have not required treatment for 2 years. Patient with baso cellular skin cancer are allowed.
• Patients with known / evidence of brain metastases are excluded from participation in this clinical trial.
• History of allergic reactions attributed to compounds of similar chemical or biologic composition to paclitaxel, carboplatin, or cisplatin or other agents used in study.
• Uncontrolled inter-current illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.
• Patients who are pregnant or breastfeeding
• Any other condition that would, in the Investigator*s judgment, contraindicate the patient*s participation in the clinical study due to safety concerns or compliance with clinical study procedures, e.g., infection/inflammation, intestinal obstruction, unable to swallow medication, social/ psychological issues.

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):	15-03-2022
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	28-10-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-12-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-01-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-05-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-01-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL76138.058.20