Study about clinical characteristics and molecular markers of carcinosarcoma of the uterus

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

Summary

ID

NL-OMON51322

Source
ToetsingOnline

Brief title
CUS II

Condition

- Reproductive neoplasms female malignant and unspecified
- Cervix disorders (excl infections and inflammations)

Synonym
cancer of the uterus, carcinosarcoma of the uterus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biomarkers, Carcinosarcoma of the uterus, Clinical outcome, Molecular analysis

Outcome measures

Primary outcome

molecular characterization of the obtained tumor tissue, liquid biopsies and

papsmear.

Secondary outcome

Quality of life-questionnaires and registration of clinical outcomes of

included subjects.

Study description

Background summary

Carcinosarcoma of the uterus (CSU) is a rare and aggressive tumor with a poor prognosis. (1) CSU has a high rate of relapse and a poor response on adjuvant therapy. Due to this aggressive character, CSU is often excluded from clinical studies on endometrial cancer and therefore little is known about optimal treatment.
There are only few studies on common genomic alterations in CSU. Even less is known about the relation between molecular alterations and clinical outcomes.
At the Erasmus MC the *carcinosarcoma of the uterus-study* (CUS) started 6 years ago with the aim to describe clinical outcomes and report the quality of life via questionnaire. In addition with this new study we hope to combine knowledge of the molecular characteristics with the clinical outcome to have better understanding about the CSU, to find markers for targeted therapy and early diagnosis to eventually increase the prognosis.

Study objective

The primary objective is to gain more insight in molecular alterations in CSU by performing a broad set of molecular analysis on tissue and blood of patients with carcinosarcoma of the uterus and find (bio)markers which can be linked to the clinical outcome or targets for adjuvant therapy.

Study design

This is an observational and exploratory study with molecular analysis on tissue, liquid biopsies (blood) and papsmear; and describing the clinical outcomes and quality of life questionnaires.

Study burden and risks

Blood will be drawn before treatment, after first chemotherapy (if applicable), pre-operative, after surgery (if applicable), at the end of treatment and 1 year after end of treatment. Also in case of a relapse, we want to analyse the blood. These timepoints are as much as possible combined with the routine outpatient clinics after treatment, to reduce the burden. There is a preference that this will be combined with blood drawn for clinical purposes. We need 20 mL of blood per time point
Molecular analysis will be performed on residual tumor tissue which has been obtained already for diagnosis and treatment. As this study will not change treatment nor randomize patients, participation in this study will not change patient outcome. The goal is to find targets for future therapies, therefore participants will not benefit from the findings of this study

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

Female patients older than 18 year who are diagnosed with a histologically confirmed CSU. Patients will be asked to sign informed consent.
Patients are also able to choose if they want to participate in a part of the study (molecular analysis, registration of clinical outcomes and/or participation in quality of life questionnaires). Patients who are already included for the CUS-study can for additionally join the CUS II study for the molecular analysis.

Exclusion criteria

Patients who are not able to fill in the questionnaires due to language (Dutch) or who are not mentally competent are excluded for the part of quality of life.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-12-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL82192.078.22