Granulosa cell tumours: a step towards targeted therapy

Published: 17-04-2018
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Primary objective:To identify common mutations or other genetic alterations and their potential as therapeutic targets in granulosa cell tumours, by studying human granulosa cell tumour specimens and establishing 3D organoid cell cultures derived...

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

Summary

ID

NL-OMON54607

Source
ToetsingOnline

Brief title
The Granulosa study

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
granulosa cell tumour, Ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Granulosafonds Philine van Esch

Intervention

Keyword: granulosa, granulosa cell tumour, ovarian cancer, ovarian tumour

Outcome measures

Primary outcome

The main endpoint of the proposed investigation is the identification of novel therapeutic targets in granulosa cell tumours, by first identifying common mutations or other genetic alterations and subsequently performing drug screens in tumour organoid cell cultures to study the effect of targeting the observed aberrations in human granulosa cell tumour samples.

Secondary outcome

The presence of circulating tumour DNA (ctDNA) in plasma of granulosa cell tumour patients, and its value as a diagnostic marker for tumour load.

Study description

Background summary

Granulosa cell tumours are non-epithelial ovarian malignancies that account for approximately 2% of ovarian cancers. Although they are often diagnosed at an early stage and the prognosis is generally favorable, recurrences occur in one third of patients and lead to higher morbidity and mortality rates. A better insight in the molecular background of granulosa cell tumours may offer novel treatment options.

Study objective

Primary objective:
To identify common mutations or other genetic alterations and their potential as therapeutic targets in granulosa cell tumours, by studying human granulosa cell tumour specimens and establishing 3D organoid cell cultures derived from human granulosa cell tumours.

Secundary objective:

To investigate if certain nanoparticles found in the blood of granulosa cell tumour patients, such as circulating tumour DNA (ctDNA) and exosome vesicles (EVs), can be used as a biomarker in the diagnostic work-up and follow-up of granulosa cell tumours.

Study design

National multi-center cohort study.

Study burden and risks

Participation in our study will be associated with very minor discomfort. There are no risks of participation, as we will be using granulosa cell tumour tissue that is either removed during routine surgery and not needed by the pathologist for histologic analysis, or has been stored after a surgery in the past. The only physical discomfort will be the collection of blood samples, if it cannot be combined with regular blood draws required for diagnosis or follow-up. If we combine the blood collection with regular blood tests, which we plan to do for the majority of blood samples, the small amount of additional blood that will be needed (two tubes) will likely not cause any discomfort. In addition, we do not expect any site visits other than the regular medical visits, nor any questionnaires or diaries to be filled in.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Women (of any age)
o Diagnosed with a granulosa cell tumour (now or in the past) OR;
o Suspected of a GCT, scheduled for surgery

Exclusion criteria

If histopathological examination after surgery shows a diagnosis other than a granulosa cell tumour, this patient will be excluded and will not be followed during the study period.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	29-05-2018
Enrollment:	355
Type:	Actual

Ethics review

Approved WMO Date:	17-04-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	19-07-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-09-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-05-2025

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL63786.041.17