BRCA mutations and ovarian ageing in normo-ovulatory women

Published: 23-09-2011
Last updated: 28-04-2024

Primary objective: To confirm that a BRCA-mutation is a determinant of advanced ovarian ageing by using serum-AMH as ovarian reserve test.Secondary objective: To confirm that a BRCA-mutation is a determinant of reduced reproductive health/outcome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menopause related conditions
Study type	Observational invasive

Summary

ID

NL-OMON37959

Source
ToetsingOnline

Brief title
BRAVA-study

Condition

- Menopause related conditions

Synonym
ageing of the ovaries, ovarian ageing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: AMH, BRCA-mutation, ovarian ageing

Outcome measures

Primary outcome

Ovarian ageing, measured by age specific serum AMH level.

Secondary outcome

Reproductive health/outcome, which is measured by:

- subfertility

- fertility treatment

- parity

- miscarriage/abortion

- life birth (and gender outcome)

- pregnancy success rate (number of pregnancies/ amount of life birth)

Study description

Background summary

Timing of menopause is associated with preceding infertility and multiple women*s health risks, such as breast, endometrial and ovarian cancer, osteoporosis, cardiovascular diseases, cognition, sexual health and general well being. Therefore, studies on factors that determine age at menopause or ovarian ageing can help us unravel the underlying biological pathways and the mechanisms of the associated infertility and health risks.
In recent literature, there remains uncertainty about the impact of BRCA gene mutations on ovarian reserve and age of natural menopause.

In the current study, by comparing serum AMH levels between cohorts of normo-ovulatory BRCA (BReast CAncer) mutation-positive women and normo-ovulatory controls, we will be able to study the effect of BRCA mutations on ovarian ageing.

The primary hypothesis is that normo-ovulatory women with a BRCA gene mutation have lower levels of AMH compared to normo-ovulatory BRCA mutation negative women, with at least a difference of 0.40 ng/ml, suggesting an effect size of three years in menopausal age.

Study objective

Primary objective: To confirm that a BRCA-mutation is a determinant of advanced ovarian ageing by using serum-AMH as ovarian reserve test.

Secondary objective: To confirm that a BRCA-mutation is a determinant of reduced reproductive health/outcome.

Study design

Cross-sectional and multi-center.

Study burden and risks

The risks associated with participation are negligible. For the prospectively approached group, blood sampling for measuring the AMH level can be done in once with taken the blood sample for genetic testing. For the retrospectively approached group, one extra visit to the hospital is necessary for blood sampling. Furthermore, the questionnaire is not likely to provide psychological injury.

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 with an age ranging between 18-45 years
Women with predictive genetic testing on BRCA mutation due to family history, or women with a known BRCA mutation carrier status
regular menstrual cylce
written informed consent

Exclusion criteria

surgical menopause
ovarian surgery
chemo-or radiation therapy
Known human immunodeficiency virus (HIV) infection
Known endocrine or autoimmune abnormalities
genetic abnormalities, others than a BRCA mutation, associated with primary ovarian insufficiency

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2012
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-05-2012
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	NL37461.041.11