BRCA mutations and ovarian Ageing in normo-oVulAtory women

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22307

Source
NTR

Brief title
BRAVA

Health condition

BRCA mutation, ovarian ageing, anti-Mullerian hormone
- Engels: AMH, BRCA, ovarian ageing
- Nederlands: AMH, BRCA, ovariele veroudering.

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

age specific AMH levels

Secondary outcome

Reproductive health/ outcome

Study description

Background summary

Rationale:
In the current study, by comparing serum anti-müllerian hormone (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 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.

Objective:

To confirm whether a BRCA mutation is a determinant of advanced ovarian ageing.

Study design:

A cross sectional multi-centre study will be performed, recruiting normo-ovulatory BRCA mutation-positive women as the case group and normo-ovulatory BRCA mutation-negative women as controls.

Study population:

The study population will be recruited by using to different approaches, a prospective and retrospective recruitment. For the prospective approach, women with an age ranging between 18 and 45 years, who present at the department of Medical Genetics for predictive BRCA mutation screening, will be asked to participate. For the retrospective, women with a current age ranging between 18 and 45 years, and with a known BRCA mutation carrier status, who have had a predictive DNA-test at the department of Medical Genetics up to 5 years earlier, are asked to participate.

Participating hospitals:

University Medical Centre (UMC) Utrecht, UMC Groningen and The Netherlands Cancer Institute/ Antoni van Leeuwenhoek Hospital, Amsterdam.

Intervention: Not applicable.

Main study endpoint:

The main study endpoint will be advanced ovarian ageing, which is primary measured by age specific AMH levels.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Burden associated with participation in the study consists of taken a blood sample, and filling out a questionnaire. Participating may be of benefit to the included women as they will receive a VVV-voucher to the value of 15 euros after providing blood and sending a completed questionnaire. Thereby, retrospective recruited participants will receive a travel allowance as stated by the UMC Utrecht.

Study objective

The primary hypothesis is that normo-ovulatory women with a BRCA 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 design

The aim is to screen and investigate a total of 120 BRCA mutation-positive and 120 BRCA mutation-negative women in a period of approximately 2.5 years. A half year is calculated for data analysis and publishing results, resulting in a total study duration of three years.

Intervention

26-jul-2014: The intervention has been a blood sample from the start of the trial. Due to misinterpretation, this was first interpreted as a therapeutical item.

Contacts

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Eligibility criteria

Inclusion criteria

- Female age between 18 and 45 years

- Predictive genetic testing on BRCA mutation or a known BRCA carrier status

- Regular menstrual cycles (i.e. mean cycle length of 21-35 days, with the next menstrual period predictable within a 7 days time frame)

- Written informed consent

Exclusion criteria

- Surgical menopause (i.e. premenopausal hysterectomy and/or bilateral ovariectomy)

- Ovarian surgery

- Chemo- or radiation therapy

- Human immunodeficiency virus (HIV) infection

- Known endocrine or autoimmune abnormalities (i.e. Cushing syndrome, type I Diabetes Mellitus, hypothyroidism, hyperprolactinemia, adrenal insufficiency, hypoparathyriodism, myasthenia gravis, rheumatoid arthritis, systemic lupus erythematosus)

- Known genetic abnormalities (structural or numerical abnormalities of the X-chromosome

(i.e. Turner’s syndrome, fragile X syndrome), or abnormalities on human autosomal functionally relevant genes, others than a BRCA mutation, associated with primary ovarian insufficiency.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-12-2013
Application type:	First submission

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
NTR-new	NL4165
NTR-old	NTR4324
Other	METC UMC Utrecht : 11-301
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A