BRCA mutations and ovarian Ageing in normo-oVulAtory women

Gepubliceerd: 18-12-2013 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22307

Bron
NTR

Verkorte titel
BRAVA

Aandoening

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

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

age specific AMH levels

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	13-01-2012
Aantal proefpersonen:	240
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	18-12-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4165
NTR-old	NTR4324
Ander register	METC UMC Utrecht : 11-301
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A