

# Cardiovascular risk after risk-reducing salpingo-oophorectomy in BRCA1/2 mutation carriers: CARSOBRA study

Published: 28-05-2015

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Primary objectives RRSO at age

|                              |                              |
|------------------------------|------------------------------|
| <b>Ethical review</b>        | Approved WMO                 |
| <b>Status</b>                | Recruitment stopped          |
| <b>Health condition type</b> | Menopause related conditions |
| <b>Study type</b>            | Observational invasive       |

## Summary

### ID

NL-OMON42246

### Source

ToetsingOnline

### Brief title

CARSOBRA study

### Condition

- Menopause related conditions
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

### Synonym

subclinical atherosclerosis; early signs of hardening of blood vessels

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** BRCA1/2 mutation, cardiovascular risk, salpingo-oophorectomy, subclinical atherosclerosis

## Outcome measures

### Primary outcome

Main study endpoints are CCA-IMT and PWV. Main study determinant is time since RRSO. Relevant covariates (confounding factors) are age, systolic blood pressure, medication use for blood pressure, smoking (pack-years of cigarette smoking and current smoking), insulin resistance, anti-diabetic medication use, fasting lipids, statin use, obstetric history of hypertensive disorders, family history of premature atherosclerosis (MI/stroke of first degree family: men < 55 years, women < 65 years), body mass index, waist-hip ratio, physical activity, menopausal symptoms, current or previous use of hormone replacement therapy and a history of breast cancer treated with chemotherapy and/or radiotherapy.

### Secondary outcome

menopausal symptoms assessed with Greene Climacteric Scale

## Study description

### Background summary

Early menopause leads to an increased cardiovascular (CV) risk which might be more pronounced in women with artificial menopause compared to natural menopause. BRCA1/2 mutation carriers are generally exposed to an earlier surgical menopause, because they are strongly recommended to undergo a risk-reducing salpingo-oophorectomy (RRSO) around the age of 40 to reduce their elevated risk of ovarian cancer. Until now, CV risk in BRCA1/2 mutation carriers after RRSO is not yet studied.

CV risk assessment based on traditional risk factors often underestimates the actual risk in middle-aged women. Measures of subclinical atherosclerosis such as increased pulse wave velocity (PVW) and common carotid artery intima-media thickness (CCA-IMT) predict future CV events in this group.

## **Study objective**

Primary objective

Is RRSO at age  $\leq 45$  in BRCA1/2 mutation carriers a risk factor for development of subclinical atherosclerosis, independent of traditional cardiovascular risk factors?

Secondary objective

Are menopausal symptoms in BRCA1/2 mutation carriers with RRSO  $\leq 45$  years associated with subclinical atherosclerosis?

## **Study design**

a single-institute cohort study

## **Study burden and risks**

The extent of burden associated with participation will be very low.

Participants will be asked to fill in a questionnaire once. Furthermore, all women will be invited for a single visit to participate in a cardiovascular screening program at the Radboudumc in Nijmegen. One blood sample will be collected and non-invasive measurements of atherosclerosis will be performed using ultrasound. In total, it will consist a time investment of approximately two hours.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Women carrying a BRCA1 or BRCA2 mutation

RRSO at age 45 or younger

RRSO performed at least five years ago

### Exclusion criteria

Women with (previous) ovarian cancer

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 17-06-2015

|             |        |
|-------------|--------|
| Enrollment: | 250    |
| Type:       | Actual |

## Ethics review

|                    |                                      |
|--------------------|--------------------------------------|
| Approved WMO       |                                      |
| Date:              | 28-05-2015                           |
| Application type:  | First submission                     |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO       |                                      |
| Date:              | 08-07-2015                           |
| Application type:  | Amendment                            |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO       |                                      |
| Date:              | 03-09-2015                           |
| Application type:  | Amendment                            |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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     | NL51609.091.15 |