the STIM-trial

Gepubliceerd: 06-08-2013 Laatst bijgewerkt: 13-12-2022

A low peak E2 during COS is considered to be safer than a high peak E2 in women with breast cancer

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21429

Bron
NTR

Verkorte titel
STIM-trial

Aandoening

breast cancer, controlled ovarian stimulation, estradiol, tamoxifen, letrozole.

borstkanker, ovariele stimulatie, oestradiol, tamoxifen, letrozol.

Ondersteuning

Primaire sponsor: Academical Medical Center
Overige ondersteuning: Pink Ribbon

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is number of oocytes retrieved at follicle apsiration.

Toelichting onderzoek

Achtergrond van het onderzoek

Raionale:Chemotherapy for breast cancer may have a negative impact on reproductive function due to gonadotoxic damage.
Fertility preservation via banking of oocytes or embryos after controlled ovarian stimulation with FSH (COS) may increase the likelihood of a future successful pregnancy. It has been hypothesized that elevated serum estrogen levels during COS may induce growth of breast tumours. This has led to the use of alternative COS protocols with addition of tamoxifen or letrozole. The effectiveness of these COS protocols in terms of oocyte yield is unknown.

Objective:To evaluate the effectiveness of COS with tamoxifen or letrozole in terms of oocyte yield compared to standard COS for oocyte- or embryo banking.

Study design:Randomized open-label trial comparing COS plus tamoxifen and COS plus letrozole with standard COS in the course of fertility preservation.

Study population:Women with breast cancer who opt for banking of oocytes or embryos, aged 18 – 43 years at randomisation.

Intervention : Women will receive tamoxifen 60 mg per day

orally in combination with COS or letrozole 5 mg per day

orally in combination with COS, or standard COS.

Main study parameters/endpoints: Primary outcome: the number of oocytes retrieved at follicle aspiration. Secondary outcomes are number of mature oocytes retrieved, number of oocytes or embryos banked and peak E2 levels during COS.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:All women will undergo one additional blood sample on the day of ovulation trigger for E2 measurement. If measurement of anti-mullerian hormone (AMH) is not part of standard care, one extra blood sample will be drawn for AMH measurement. In the women who receive tamoxifen in addition to COS, in some centres (Academic Medical Center Amsterdam and University hospital Brussels a series of four to six measurements of tamoxifen metabolites will be analysed in blood samples acquired during routine blood sampling for COS.

Multiple changes are made at 21-may-2015

Doel van het onderzoek

A low peak E2 during COS is considered to be safer than a high peak E2 in women with breast cancer

Onderzoeksopzet

1. during COS at day of ovulation trigger with GnRHa

2. day of OPU (number of cryopreserved embryo's or oocytes)

Onderzoeksproduct en/of interventie

Group 1 will receive tamoxifen (60 mg per day, orally) in addition to COS. Group 2 will receive letrozoel (5 mg per day, orally) in addition to COS. Group 3 will undergo standard COS with no additional treatment.

Contactpersonen

Publiek

Academic medical centre, location Q3-120
Postbus 22660
M. Goddijn
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663557

Wetenschappelijk

Academic medical centre, location Q3-120
Postbus 22660
M. Goddijn
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663557

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 18 – 43 years

- Confirmed breast cancer (ER+, ER- or unknown ER status)

- Candidate for oocyte or embryocryopreservation (as approved by referring breast cancer specialist and the centre for reproductive medicine that the women is referred to)

- Willing and able to give informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Contraindication to study medication
- Use of medication that opposes effect of study medication

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-08-2013
Aantal proefpersonen:	159
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:	06-08-2013
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	NL3942
NTR-old	NTR4108
Ander register	NA : 43808
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A