the STIM-trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21429

Source
Nationaal Trial Register

Brief title
STIM-trial

Health condition

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

borstkanker, ovariele stimulatie, oestradiol, tamoxifen, letrozol.

Sponsors and support

Primary sponsor: Academical Medical Center
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Outcome measures

Primary outcome

Primary outcome is number of oocytes retrieved at follicle apsiration.

Secondary outcome

- Number of mature oocytes retrieved

- Number of oocytes or embryos banked

- Peak E2 levels during COS defined as serum E2 level measured on the day of ovulation trigger

Study description

Background summary

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

Study objective

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

Study design

1. during COS at day of ovulation trigger with GnRHa
2. day of OPU (number of cryopreserved embryo's or oocytes)

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2013
Enrollment:	159
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-08-2013
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	NL3942
NTR-old	NTR4108
Other	NA : 43808
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A