Stimulation of the ovaries in women with breast cancer undergoing fertility preservation: alternative versus standard stimulation protocols; the STIM-trial

Published: 31-07-2013
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To evaluate the effects of COS with tamoxifen or letrozole compared to standard COS, on oocytes retrieved.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON47167

Source
ToetsingOnline

Brief title
STIM-trial

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Gonadotrophin and sex hormone changes

Synonym
breast cancer, mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Pink Ribbon (charitatieve instelling)

Intervention

Keyword: breast cancer, estrogens, fertility preservation

Outcome measures

Primary outcome

- Number of oocytes retrieved

Secondary outcome

- Number of mature (metaphase II) oocytes

- Number of oocytes or embryo''s cryopreserved

- Peak estradiol levels during COS (measured at the day of ovulation trigger).

- Levels of active tamoxifen metabolites (only in women randomised to use tamoxifen)

- Data regarding long-term outcomes will be collected but is not part of current studyprotocol.

Study description

Background summary

Chemotherapy for breast cancer may have a negative impact on reproductive function due to gonadotoxic damage. Cryopreservation of oocytes or embryos after IVF with controlled ovarian stimulation with FSH (COS) may increase the likelihood of future successful pregnancy, when this is performed prior to chemotherapy. It has been hypothesized that elevated estrogen levels during COS may induce growth of hormone sensitive tumours. This has led to the use of alternative COS protocols with addition of tamoxifen or letrozole. The idea is

that these agents reduce oestradiol levels during COS. It is unknown if stimulation protocols with additional agents influence the oocyte retrieved. The aim of this study is to evaluate the effectiveness of COS with tamoxifen or letrozole compared to standard COS in women with breast cancer who opt for oocyte- or embryocryopreservation.

Study objective

To evaluate the effects of COS with tamoxifen or letrozole compared to standard COS, on oocytes retrieved.

Study design

Randomized open-label trial comparing COS with additional tamoxifen or letrozole with standard COS.

Intervention

The first group of women will receive standard COS with tamoxifen 60 mg per day orally. The second group of women will receive standard COS with Letrozole 5 mg per day orally. The third group will receive standard COS

Study burden and risks

All women will undergo one additional blood sample on the day of ovum pick up for estradiol (E2) measurement. In the women who receive tamoxifen in addition to standard COS, a series of four to six measurements of tamoxifen metabolites will be analysed in bloodsamples aquired during routine bloodsampling for COS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 * 43 years
Confirmed breast cancer (ER+, ER- or unknown ER status)
Candidate for (neo) adjuvant chemotherapy
Opting for embryo- or oocyte cryopreservation
Willing and able to give informed consent

Exclusion criteria

Contraindication to study medication
Use of medication that opposes effect of study medication
Current use of tamoxifen or letrozolr

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2014
Enrollment:	149
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	letrozole
Generic name:	letrozole
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	tamoxifen
Generic name:	tamoxifen
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	31-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	26-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	01-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	16-10-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-11-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-05-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-11-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2013-000801-21-NL
CCMO	NL43808.018.13