Ovarian hyperstimulation in women with estrogen-receptor positive breastcancer who opt for embryo- or oocyte freezing: Is the Tamoxifen dosage sufficient to protect women against estrogen exposure? (TAMOXI project: a pilot study).

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The objective of this pilot-study is to investigate if the current dosage of tamoxifen supplied to women with estrogen receptor positive breastcancer who opt for embryo- or oocyte freezing is protective during the whole period of hormone stimulation…

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON35875

Source
ToetsingOnline

Brief title
TAMOXI project

Condition

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

Synonym

breastcancer, mammary carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breastcancer, estrogen blockade, ovarian hyperstimulation, tamoxifen

Outcome measures

Primary outcome

The primary outcome of the study is the serum endoxifen level during the whole period of ovarian hyperstimulation.

The endoxifen level is a binary outcome measure, a level < 7 ng/ml = supposed to be insufficient E2 blockade.

Secondary outcome

Baseline characteristics, ovarian hyperstimulation, the resulting number and quality of embryos and oocytes frozen. Data with regard to the cycle day, hour of tamoxifen intake and the hour of blood sample and follicle-fluid collections for measurement of active tamoxifen-metabolites are collected as well.

Study description

Background summary

Significant medical advances in cancer treatment have improved survival rates in female cancer survivors of reproductive age and as a consequence, the wish to have children has become increasingly important. Fertility preservation

techniques (e.g. ovarian, embryo and oocyte freezing) are now available to increase chances of further childhood, and these techniques need to be performed just prior to gonadotoxic treatment, like radiotherapy or chemotherapy.
The Centre for Reproductive Medicine, AMC, employs embryo and oocyte freezing. Women who opt for embryo or oocyte freezing will receive hormone stimulation with GnRH analogues and recombinant FSH injections during a 2-3 weeks period and subsequently undergo ovum pick up with the aim to freeze embryos or oocytes.
In women with breast cancer and estrogen positive hormone receptors, hormone-stimulation may induce extra growth of cancer cells. The additional use of 60 mg of tamoxifen is supposed to block the effect of high estrogen levels. Until now it is unknown what dosage of tamoxifen is regarded as a sufficient to protect women for the high levels of estrogens that arise during ovarian hyperstimulation. In this pilot-study we will investigate the protective effect of Tamoxifen by measuring the level of its active metabolites (endoxifen, N-desmethyltamoxifen, 4-hydroxytamoxifen, 4*-hydroxytamoxifen en N-desmethyl-4*-hydroxytamoxifen). Below a certain endoxifen level (< 7 ng/ml) the estrogen receptor modulation in estrogen sensitive breast cancer receptors is supposed to be insufficient. To this aim we want to investigate if the dosage of tamoxifen given is protective during the whole period of hormone stimulation.

Study objective

The objective of this pilot-study is to investigate if the current dosage of tamoxifen supplied to women with estrogen receptor positive breastcancer who opt for embryo- or oocyte freezing is protective during the whole period of hormone stimulation.

Study design

Tamoxifen (60 mg daily) is administered to women who opt for embryo or oocyte freezing who suffer from breast cancer and estrogen positive hormone receptors. During ovarian hyperstimulation, four to five blood samples in these women are taken on a routine base with measurements of the levels of estradiol (E2) and luteinizing hormone (LH) in order to measure the effect of ovarian stimulation. After given informed consent, an extra blood sample is collected at every moment of routine blood collection to the aim of measuren the concentrations of active tamoxifen-metabolites (endoxifen, N-desmethyltamoxifen, 4-hydroxytamoxifen, 4*-hydroxytamoxifen en N-desmethyl-4*-hydroxytamoxifen). We will also perform measurements of these metabolites in remained follicle-fluid that is collected after ovum-pick up.

Study burden and risks

There are no risks associated with participation of the study.

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

Women who are of reproductive age (18- 40 yrs), who suffer from estrogen- receptor positive breast cancer and opt for embryo- or oocyte freezing.

Exclusion criteria

1)Women who are unwilling or unable to sign the informed consent form
2)Women who are not in good enough medical condition to undergo ovarian hormone

stimulation and ovum pick up.
3) Women who need medication which opposes the efficacy of tamoxifen (e.g. fluotexine)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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
CCMO	NL35447.018.11