The protective effect of tamoxifen in women with ER-positive breast cancer who opt for cryopreservation of oocytes or embryos: a prospectively controlled study.

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Ethical review	Not approved
Status	Will not start
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON36860

Source
ToetsingOnline

Brief title
Tamoxi-study

Condition

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

Synonym
breast cancer, 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: breast cancer, estrogen blockade, ovarian stimulation, tamoxifen

Outcome measures

Primary outcome

Number of women who reach a serum endoxifen above the threshold level of 5.9

ng/ml during COS.

Secondary outcome

Secundary parameters are:

- Levels of serum tamoxifen metabolites in the course of ovarian stimulation.

- Estradiol levels in the course of ovarian stimulation.

- Number of oocytes or embryo*s retrieved and cryopreserved after ovarian

stimulation.

- Ongoing pregnancy rate.

- Breast cancer recurrence free survival after 60 and 120 months.

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. Different centers in the Netherlands employ embryo and/or 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 ER-positive breast cancer, hormone-stimulation may induce extra growth of cancer cells. The additional use of 60 mg of tamoxifen may block the effect of high estrogen levels. Until now it is unknown what dosage of tamoxifen is regarded as sufficient to protect women for the high levels of estrogens that arise during ovarian hyperstimulation. In this 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 (< 5,9 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 study is to investigate the relation between tamoxifen use during COS, endoxifen levels reached during COS, and recurrence-free survival (locoregional recurrence, distant recurrence or death from any cause) when compared with matched controls who did not undergo COS.

Study design

Pharmacokinetic effects of tamoxifen will be studied in a prospective longitudinal cohort study. A nested case control study will be made comparing 40 cases -women with ER-positive breast cancer using tamoxifen in combination with COS- with 120 age matched women with ER-positive breast cancer who do not opt for fertility preservation, but started tamoxifen as standard adjuvant therapy. Another 120 women will be followed up by looking at recurrence free survival after 5 and 10 years. These women will be matched by tumour characteristics.

Study burden and risks

Except for the minor risk of a hematoma as a consequence of the venous blood sampling, 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

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

Exclusion criteria

Contraindication to tamoxifen use
Use of medication that opposes the effect of study medication
Pregnancy or lactation
Recent chemotherapy
Liver- or kidney failure

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Not approved

Date:	13-03-2013
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	NL41102.018.12