A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy

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Primary objectiveTo assess the risk of breast cancer relapse associated with temporaryinterruption of endocrine therapy (ET) to permit pregnancy.Secondary objectiveTo evaluate factors associated with pregnancy success after interruption ofendocrine...

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

Summary

ID

NL-OMON42456

Source
ToetsingOnline

Brief title
POSITIVE study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Sexual function and fertility disorders

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: IBCSG Coordinating Center
Source(s) of monetary or material Support: KWF

Intervention

Keyword: breast cancer, endocrine therapy, pregnancy

Outcome measures

Primary outcome

Primary endpoint:

Breast cancer free interval (BCFI) defined as the time from enrollment in the study to the first invasive BC event (local, regional, or distant recurrence or a new invasive contralateral BC).

Secondary outcome

Secondary endpoints:

Menstruation recovery and pattern.

Pregnancy (determined by pregnancy test).

Pregnancy outcome: full term pregnancy, caesarean section, abortion, miscarriage, ectopic, stillbirth.

Offspring outcome: preterm birth, low birth weight, birth defects.

Breastfeeding; pattern of breastfeeding (duration, use ipsilateral breast if previous breast conservation, side exclusivity).

Use of assisted reproductive technology (ART).

Adherence to endocrine treatment assessed by:

- Treatment resumption after the ~2 year ET break.

- Total duration of at least 5 years of ET.

Distant recurrence-free interval (DRFI), defined as the time from enrollment in

the study to the first BC recurrence in a distant site,

excluding second (non-breast) primary cancers and contralateral breast cancer.

Study description

Background summary

Breast cancer in young women often occurs before the completion of reproductive plans. Infertility has a significant impact on quality of life, resulting in substantial distress in younger women with breast cancer and influencing treatment decisions in a consistent proportion of patients. For women desiring pregnancy after a breast cancer, 5-10 years of ET may substantially reduce the chance of conception; however, a shorter duration of ET in this population has not been studied in a prospective manner. The best available evidence suggests that pregnancy after breast cancer does not increase a woman*s risk of developing a recurrence. Birth outcome after breast cancer has not been shown to be different from that of the normal population, but increased risks of delivery complications, cesarean section, preterm birth and low birth weight have been reported. Endocrine agents are potentially teratogenic: taking into account their median half-life, waiting 3 months after their interruption before attempting conception is considered safe. The limited evidence available on breastfeeding after breast cancer reports successful lactation from the treated breast in approximately 30% of women without detrimental effect on survival. Currenty there are no prospective data.

Study objective

Primary objective
To assess the risk of breast cancer relapse associated with temporary interruption of endocrine therapy (ET) to permit pregnancy.

Secondary objective
To evaluate factors associated with pregnancy success after interruption of endocrine therapy.

Study design

A single-arm, phase II trial evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy

Study burden and risks

Burden: extra bloodsampling and outpatient clinic visits
Risks: prospectively unkown if interruption of hormonal therapy after 18-30 monthes is safe for breast cancer ercurrence

Contacts

Public
IBCSG Coordinating Center

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Scientific
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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 and * 42 years at enrollment.
-Has received adjuvant endocrine therapy (SERM alone, GnRH analogue plus SERM or AI) for *18 months but *30 months for early breast cancer.
-The adjuvant endocrine therapy must have stopped within 1 month prior to enrollment.

- Patient wishes to become pregnant.
- Breast cancer for which patient is receiving endocrine therapy must have been histologically-proven stage I-III, endocrine-responsive (i.e., estrogen and/or progesterone receptor positive, according to local definition of positive, determined using immunohistochemistry (IHC)), and treated with curative intent.
-Patient must be premenopausal at breast cancer diagnosis, as determined locally and documented in patient record.
-Patient must be without clinical evidence of loco-regional and distant disease, as evaluated according to institutional assessment standards and documented in the patient record.
- Written informed consent (IC) for trial participation *
- Written consent to biological material submission
- The patient has been informed of and agrees to data transfer and handling, in accordance with national data protection guidelines.
-Patient must be accessible for follow-up.

Exclusion criteria

- Post-menopausal patients at BC diagnosis, as determined locally.
- History of hysterectomy, bilateral oophorectomy or ovarian irradiation.
- Patients with current local, loco-regional relapse and/or distant metastatic breast cancer.
- Patients with a history of prior (ipsi- and/or contralateral) invasive BC.
- Patients with previous or concomitant non-breast invasive malignancy. Exceptions are limited exclusively to patients with the following previous malignancies, if adequately treated: basal or squamous cell carcinoma of the skin, in situ non-breast carcinoma, contra- or ipsilateral in situ breast carcinoma, stage Ia carcinoma of the cervix.
- Concurrent disease or condition that would make the patient inappropriate for study participation or any serious medical disorder that would interfere with the patient*s safety.
- Patients with a history of noncompliance to medical treatments and/or considered potentially unreliable.
- Patients with psychiatric, addictive, or any disorder that would prevent compliance with protocol requirements.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-11-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT02308085
CCMO	NL54300.058.15