Early prediction of menopausal status in pre/perimenopausal women with early breast cancer after (neo) adjuvant chemotherapy in order to optimize adjuvant endocrine therapy

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Can absolute AMH levels, measured before start of (neo)adjuvant chemotherapy, correctly predict recovery of ovarian function within the first two years following (neo)adjuvant chemotherapy in pre/perimenopausal patients with early breast cancer?

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28140

Bron
NTR

Verkorte titel
AMH study

Aandoening

primary hormone receptor positive breast cancer

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: Pink Ribbon

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

recovery of ovarian function is defined as resumption of menstrual cyclicity (at least more than 1 episode of vaginal bleeding, not caused by vaginal atrophy) and/or levels of estradiol and FSH in the postmenopausal range (according to the local laboratory values; in general >110 pmol/l and <20 pmol/l, respectively), being reconfirmed at least once.

Toelichting onderzoek

Doel van het onderzoek

Can absolute AMH levels, measured before start of (neo)adjuvant chemotherapy, correctly predict recovery of ovarian function within the first two years following (neo)adjuvant chemotherapy in pre/perimenopausal patients with early breast cancer?

Onderzoeksopzet

nvt

Onderzoeksproduct en/of interventie

no intervention

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria:

• Primary hormone-sensitive (ER >10% positive and/or PgR >10% positive) breast cancer, independent of Her2- receptor status, curatively locally treated

• Age 46 years

• Indication for (neo-)adjuvant chemotherapy according to the Dutch Guidelines for breast cancer treatment (2012)

• Pre- (regular menstrual cyclicity) and perimenopausal women (amenorrhea duration of less than 12 months) before the start of (neo-) adjuvant chemotherapy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria:

• Bilateral oophorectomy

• History of hysterectomy (no information on menstrual cycle possible)

• Evidence of distant metastases

• Use of GnRH agonists within 12 months before the start of (neo-) adjuvant chemotherapy

• Use of hormone-containing intra-uterine device (Mirena®), irrespective of age at breast cancer diagnosis (use of copper-containing devices is allowed)

• Chemotherapy prior to inclusion in the study

• Use of aromatase inhibitors or tamoxifen <6 months before start of (neo-) adjuvant chemotherapy

• History of pelvic radiatiotherapy

• History of treatment with cytotoxic chemotherapy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2013
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-11-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5343
NTR-old	NTR5575
Ander register	Erasmus Medical Center : MEC13-156

Resultaten

Samenvatting resultaten
not yet