ADHERE
ADherence to ADjuvant HormonE theRapiEs
The association between illness perceptions and adherence to endocrine therapies in patients with breast cancer

Gepubliceerd: 15-04-2020 Laatst bijgewerkt: 13-12-2022

To study the predictive value of illness perceptions, fear of cancer recurrence, medication beliefs and quality of life on adherence to endocrine treatment at 12 months. To study adherence to endocrine therapy at 3 and 6 months. To compare cross-...

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

Samenvatting

ID

NL-OMON19944

Bron
NTR

Verkorte titel
ADHERE

Aandoening

This study will include women with stage I-III breast cancer who are scheduled to receive adjuvant ET without adjuvant chemotherapy

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To study the predictive value of illness perceptions, fear of cancer recurrence, medication beliefs and quality of life on adherence to endocrine treatment at 12 months

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Illness perceptions (IPs), medication beliefs, Fear of cancer recurrence (FCR) and quality of life (QoL) may influence adherence to endocrine therapy (ET) in patients with breast cancer.

Objective: To analyze the predictive value of IPs, medication beliefs and QoL on adherence to adjuvant ET and to create a prediction model with adherence as outcome.

Study design: Descriptive study.

Study population: Women with stage I-III breast cancer treated for their disease at the Leiden University Medical Center, the Haaglanden Medical Center and the Saitama Cancer Center in Japan.

Main study parameters/endpoints: Adherence to ET in the first year in patients with early breast cancer and its association with illness perceptions, medication beliefs and QoL.

Doel van het onderzoek

To study the predictive value of illness perceptions, fear of cancer recurrence, medication beliefs and quality of life on adherence to endocrine treatment at 12 months.

To study adherence to endocrine therapy at 3 and 6 months.
To compare cross-cultural differences of illness perceptions, medication beliefs, quality of life and adherence to ET in women with breast cancer.
To determine the ability to retain/resume work.
To observe and evaluate occurrence of side effects (grade III/IV).

Onderzoeksopzet

Patients will be asked to fill out multiple questionnaires at the following time points; at

baseline and after 3, 6 and 12 months of starting with endocrine therapy.

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

LUMC
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071-5263121

Wetenschappelijk

LUMC
Jony Bruin

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

This study will include women with stage I-III breast cancer who are scheduled to receive adjuvant ET without adjuvant chemotherapy. Patients will be recruited from the Leiden University Medical Center in the Netherlands, the Haaglanden Medical Center in the Netherlands and the Saitama Cancer Center in Japan.

To be eligible to participate in this study, a subject must meet all of the following criteria:
• Female patients aged 18 years or older;
• Stage I, II or III HR-positive breast cancer;
• Scheduled adjuvant endocrine therapy.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Patients with M+ tumors;
• Patients receiving neoadjuvant endocrine therapy;
• Patients receiving (neo)adjuvant chemotherapy;
• Patients with other types of active cancer within the past 3 years;
• Previous use of endocrine therapy or chemotherapy;
• Medical or psychological condition which, in the opinion of the investigator, would not permit the patient to complete the study or sign meaningful informed consent.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2020
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-04-2020

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	NL8541
Ander register	METC-LDD : N19.122

Resultaten