

# ADHERE

## ADherence to ADjuvant HormonE theRapiEs

### The association between illness perceptions and adherence to endocrine therapies in patients with breast cancer

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON19944

### Source

NTR

### Brief title

ADHERE

### Health condition

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

## Sponsors and support

**Primary sponsor:** none

**Source(s) of monetary or material Support:** none

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

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).

## Study description

### Background summary

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.

### Study objective

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).

## **Study design**

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.

## **Intervention**

none

## **Contacts**

### **Public**

LUMC

Jony Bruin

071-5263121

### **Scientific**

LUMC

Jony Bruin

071-5263121

## **Eligibility criteria**

### **Inclusion criteria**

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.

## Exclusion criteria

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.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	200
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	15-04-2020

Application type:

First submission

## 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
NTR-new	NL8541
Other	METC-LDD : N19.122

## Study results