

Patients' expectations and experiences of abemaciclib and hormone therapy for early-stage high-risk breast cancer

Submission date 05/10/2021	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/10/2021	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/12/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study is looking at the expectations and experiences of women who are receiving abemaciclib (also called Verzenios) and hormone therapy for early breast high-risk cancer. Abemaciclib is called a targeted therapy. These targeted cancer drugs are treatments that help the body to control the growth and spread of cancer. They focus on specific abnormalities within cancer cells that allow them to survive. When used in breast cancer, abemaciclib is taken together with hormone therapy (also called endocrine therapy).

Treatment with abemaciclib and endocrine therapy for women with early-stage breast cancer that is at high risk of recurrence (returning) is fairly new. Little is known about what patients expect, their experiences during treatment and how they manage any possible side effects. It is known for example that diarrhoea is a common side effect of abemaciclib and can sometimes be severe. Diarrhoea usually starts during the first weeks of treatment. Finding out how people experience treatment, how well they deal with any problems and understanding their needs, is essential to aid the development of helpful information materials that will best inform and support them.

Who can participate?

Patients aged 18 years and over with breast cancer who are postmenopausal and are participating in the POETIC-A trial and allocated to receive abemaciclib and standard hormone therapy

What does the study involve?

Patients take part in a series of three interviews with researchers. They will be interviewed before starting treatment to find out what their expectations are and what they know about the drugs they have been prescribed. The follow-up interviews will take place 4 and 8 weeks later to find out if their treatment experiences met their expectations, if they experienced side effects, especially diarrhoea, what steps they have taken to reduce it, and how successful this was.

What are the possible benefits and risks of participating?

There are no direct benefits of taking part in this study, but the research findings might benefit

others in the future. The results of the study will help to get a better understanding of how treatment with abemaciclib and hormone therapy affects people. This will be used to provide the best information and support for others starting this treatment in the future.

Where is the study run from?

Sussex Health Outcomes Research & Education in Cancer (SHORE-C) and Brighton & Sussex Medical School (UK)

When is the study starting and how long is it expected to run for?

July 2021 to August 2023

Who is funding the study?

Eli Lilly and Company Limited (USA)

Who is the main contact?

Dr Helena Harder

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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

298216

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 298216, CPMS 49884

Study information

Scientific Title

Perceptions and experiences of abemaciclib and endocrine therapy

Acronym

PEATY

Study objectives

The PEATY study aims to examine patients' perceptions, attitudes, health beliefs, and experiences with abemaciclib and standard adjuvant endocrine therapy for ER+ HER2- breast cancer. The data collected in this study will provide a more comprehensive picture and important insights into the benefits, barriers and challenges associated with treatment in this high-risk population and its impact on their day-to-day life. This is important as patient-reported outcomes recorded in clinical trials reflect patient experiences while on treatment, but are limited by the content of the questionnaires used to assess outcomes. PEATY will employ mixed methods using semi-structured, in-depth interviews that focus on patients' experiences and changes over time.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/07/2021, London - Chelsea Research Ethics Committee (REC London Centre, 2 Redman Place, Stratford, London, E20 1JQ, UK; .+44 (0)207 104 8029; chelsea.rec@hra.nhs.uk), REC ref: 21/PR/0853

Study design

Multicenter observational mixed method study

Primary study design

Observational

Study type(s)

Quality of life, Treatment

Health condition(s) or problem(s) studied

Quality of life of women receiving abemaciclib and endocrine therapy for breast cancer

Interventions

Study data will be collected through three semi-structured interviews: at baseline before start of treatment, and 4 and 8 weeks later. The baseline interviews will explore patients' understanding of the drugs prescribed, expectations of treatment, and health beliefs. The follow-up interviews will capture patients' treatment experiences, in particular treatment side effects such as diarrhoea, how these impact day-to-day life, and how they are managed.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Abemaciclib

Primary outcome(s)

Patients' expectations and experiences of treatment with abemaciclib and standard adjuvant endocrine therapy for early-stage high-risk breast cancer, assessed using semi-structured interviews at baseline before the start of treatment and 4 and 8 weeks later

Key secondary outcome(s)

Patients' information and communication needs, assessed using semi-structured interviews at baseline before the start of treatment and 4 and 8 weeks later

Completion date

31/08/2023

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility**Key inclusion criteria**

1. Diagnosis of ER+, HER2- breast cancer
2. Postmenopausal
3. Participating in the POETIC-A trial and randomised to receive abemaciclib and standard adjuvant endocrine therapy
4. Aged 18 years or over
5. Good comprehension of the English language

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Total final enrolment

5

Key exclusion criteria

1. Inability to understand and speak English
2. Inability to give fully informed consent

Date of first enrolment

01/10/2021

Date of final enrolment

01/06/2023

Locations**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre

University Hospitals Dorset - Royal Bournemouth Hospital

Castle Lane East

Bournemouth

United Kingdom

BH7 7DW

Study participating centre

University Hospitals Dorset - Poole Hospital

Poole Hospital
Poole
United Kingdom
BH15 2JB

Study participating centre

Surrey and Sussex Healthcare NHS Trust - East Surrey Hospital

Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre

Shrewsbury and Telford NHS Hospital Trust - Royal Shrewsbury Hospital

Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre

South Warwickshire University NHS Foundation Trust

Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre

East Suffolk and North Essex NHS Foundation Trust

Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre

The Christie NHS Foundation Trust

550 Wilmslow Road
Withington

Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation

University of Sussex

ROR

<https://ror.org/00ayhx656>

Funder(s)

Funder type

Industry

Funder Name

Eli Lilly and Company

Alternative Name(s)

Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co, Eli Lilly & Co

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

Trial closed prematurely (under recruiting) data will not be published and for that reason not be shared

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes