ISRCTN10597735 https://doi.org/10.1186/ISRCTN10597735

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

Submission date
05/10/2021

Recruitment status
Stopped

Registration date
06/10/2021

Overall study status
Stopped

Last Edited
14/12/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
h.harder@sussex.ac.uk

Study website
https://shore-c.sussex.ac.uk/peaty.html

Contact information

Type(s)
Scientific

Contact name
Prof Lesley Fallowfield

Contact details
Sussex Health Outcomes Research and Education in Cancer (SHORE-C)
Brighton & Sussex Medical School
University of Sussex
Brighton
United Kingdom
BN1 9RX
+44 (0)1273 873019
L.J.Fallowfield@sussex.ac.uk

Type(s)
Public

Contact name
Dr Helena Harder

ORCID ID
http://orcid.org/0000-0002-7296-8227

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

University of Sussex
Brighton
United Kingdom
BN1 9RX
+44 (0)12730 873029
h.harder@sussex.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
298216

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment

Participant information sheet
https://shore-c.sussex.ac.uk/docs/PEATYpisV2.pdf

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 measure
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

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

Overall study start date
29/07/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30

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
England

Northern Ireland

Scotland

United Kingdom

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

Sponsor details
Research & Enterprise Services
Falmer House
Brighton
England
United Kingdom
BN1 9QF
+44 (0)1273 872748
researchsponsorship@sussex.ac.uk

Sponsor type
University/education

Website
http://www.sussex.ac.uk/

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

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 14/12/2023:
The researchers are trying the publish the results as a short communication in a peer-reviewed journal and are also submitting a conference abstract.

Previous publication and dissemination plan as of 14/08/2023:
The trial did not recruit sufficient patients and results will not be published in peer-reviewed journal.

Previous publication and dissemination plan:
The researchers plan to publish the findings from this research in a high-impact peer-reviewed journal. A plain language summary of the findings will be sent to all study participants and published on the study website. Additional documents are currently not available.

Intention to publish date
31/08/2024

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