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# 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**
26/05/2026

**Condition category**
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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

# 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
https://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

### Integrated Research Application System (IRAS)
298216

### Central Portfolio Management System (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

### Primary study design
Observational

### Study design
Multicenter observational mixed method study

### 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
Mixed

**Lower age limit**
18 Years

**Upper age limit**
120 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
England
BH7 7DW

**Study participating centre**
**University Hospitals Dorset - Poole Hospital**
Poole Hospital

Poole
England
BH15 2JB

**Study participating centre**
**Surrey and Sussex Healthcare NHS Trust - East Surrey Hospital**
Canada Avenue
Redhill
England
RH1 5RH

**Study participating centre**
**Shrewsbury and Telford NHS Hospital Trust - Royal Shrewsbury Hospital**
Mytton Oak Road
Shrewsbury
England
SY3 8XQ

**Study participating centre**
**South Warwickshire University NHS Foundation Trust**
Warwick Hospital
Lakin Road
Warwick
England
CV34 5BW

**Study participating centre**
**East Suffolk and North Essex NHS Foundation Trust**
Heath Road
Ipswich
England
IP4 5PD

**Study participating centre**
**The Christie NHS Foundation Trust**
550 Wilmslow Road
Withington
Manchester
England
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**

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 22/05/2026 | 26/05/2026 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |

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|---|---|---|---|---|---|
| Plain English results | | | 26/05/2026 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |