

Impact of abemaciclib on patients' roles and responsibilities

Submission date 16/06/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/12/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-the-effect-abemaciclib-has-on-the-daily-life-of-people-who-take-it-impactor>

Contact information

Type(s)

Public

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Type(s)

Scientific

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Additional identifiers**Integrated Research Application System (IRAS)**

279088

Study information**Scientific Title**

Impact of abemaciclib on patients' roles and responsibilities: a multi-centre observational quality of life study with nested qualitative interview study

Acronym

IMPACTOR

Study objectives

The principal objective of the study is to investigate breast cancer patients' experiences of abemaciclib treatment outside of a clinical trial setting. The primary aim is to chart any changes in their quality of life in the first 6 months of treatment, and the impact of this treatment on patients' ability to perform their normal roles and responsibilities. The researchers will conduct semi-structured interviews with a subset of the participants to achieve a more in-depth, richer understanding of their experiences of treatment, both positive and negative, side effects, and ways in which their day to day activities have been affected. One of the side effects more commonly associated with abemaciclib is diarrhoea. The researchers will ask participants to record their experiences of diarrhoea, and the measures they took to manage it, using a diarrhoea diary. This will enable them to assess whether treatment-related diarrhoea is manageable and decreases over time, as current trial data suggests.

Ethics approval required

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Ethics approval(s)

approved 17/04/2020, North East Tyne and Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 972 2496; tyneandwearsouth.rec@hra.nhs.uk), ref: 20/NE/0101

Study design

Multi-centre observational quality of life study with nested qualitative interview study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Quality of life of women receiving abemaciclib for breast cancer

Interventions

This is a quality of life observational study. Participants will complete validated quality of life measures at baseline, 1, 3 and 6 months and a weekly diarrhoea management diary. A subset of the participants will take part in a semi-structured qualitative interview study after 3 months.

Intervention Type

Drug

Phase

Phase III/IV

Drug/device/biological/vaccine name(s)

Abemaciclib

Primary outcome(s)

1. Quality of life assessed using the Functional Assessment of Cancer Treatment general scale (FACT-G) with diarrhoea (DS) and endocrine symptom (ES) subscale at baseline, 1, 3 and 6 months
2. Role function assessed using the Patient Roles and Responsibilities Scale (PRRS) at baseline, 1, 3 and 6 months

Key secondary outcome(s)

1. Qualitative evidence of patients' experience of treatment collected via a semi-structured interview at 3 months
2. Treatment-related diarrhoea measured using the Diarrhoea Management Diary (DMD) completed weekly for 6 months
3. Strategies employed to counter diarrhoea, including non-adherence to treatment, measured using the DMD completed weekly for 6 months

Completion date

08/03/2023

Eligibility

Key inclusion criteria

1. Patients with locally advanced or metastatic breast cancer who are prescribed either:
 - 1.1. Abemaciclib in combination with fulvestrant (for women who have relapsed after endocrine therapy), or
 - 1.2. Abemaciclib in combination with an aromatase inhibitor (for women who have not

previously been treated)

2. Patients who are able to give fully informed consent and are able to read and speak in English

3. Patients who are 18 years old and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

Female

Total final enrolment

46

Key exclusion criteria

1. Patients with cancers other than breast or receiving treatments other than abemaciclib

2. Patients who are not able to provide fully informed consent or who are not able to read and speak English

3. Patients under 18 years of age

4. Patients who are currently inpatients or who are too distressed to participate

Date of first enrolment

01/09/2020

Date of final enrolment

31/12/2022

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre

Brighton and Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
England
BN2 5BE

Study participating centre
The Clatterbridge Cancer Centre NHS Foundation Trust
Clatterbridge Road
Bebington
Wirral
England
CH63 4JY

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
London
England
SW3 6JJ

Study participating centre
The Christie NHS Foundation Trust
Wilmslow Road
Manchester
England
M20 4BX

Study participating centre
Airedale General Hospital
Airedale NHS Foundation Trust
Skipton Road
Steeton
Keighley
England
BD20 6TD

Study participating centre
Kent and Canterbury Hospital
East Kent Hospitals University NHS Foundation Trust

Ethelbert Road
Canterbury
England
CT1 3NG

Study participating centre

The Royal Bournemouth Hospital

Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
Castle Lane East
Bournemouth
England
BH7 7DW

Study participating centre

Royal Surrey NHS Foundation Trust

Egerton Road
Guildford
England
GU2 7XX

Study participating centre

Lothian Health Board

Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

Study participating centre

Yeovil District Hospital NHS Foundation Trust

Higher Kingston
Yeovil
England
BA21 4AT

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

The anonymised datasets generated during and/or analysed during the current study will be available upon (reasonable) request after publication of the findings from Sussex Health Outcomes Research and Education in Cancer (adminshore-c@sussex.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/04/2025	28/04/2025	Yes	No
HRA research summary			26/07/2023	No	No
Other publications	Qualitative analysis	26/04/2025	28/04/2025	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Plain English results			18/12/2025	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes