Impact of abemaciclib on patients' roles and responsibilities

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
16/06/2020		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
16/06/2020		[X] Results		
Last Edited	Condition category	[] Individual participant data		
28/04/2025	Cancer			

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

Study website

https://shore-c.sussex.ac.uk/impactor.html

Contact information

Type(s)

Public

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

279088

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Ethics approval required

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

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

The participant information sheet will be made available at https://shore-c.sussex.ac.uk/impactor.html

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 measure

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

Secondary outcome measures

- 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

Overall study start date

24/04/2019

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

150

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

England

Scotland

United Kingdom

Study participating centre

Brighton and Sussex University Hospitals NHS Trust

Royal Sussex County Hospital Eastern Road Brighton United Kingdom BN2 5BE

Study participating centre

The Clatterbridge Cancer Centre NHS Foundation Trust

Clatterbridge Road Bebington Wirral United Kingdom CH63 4JY

Study participating centre

The Royal Marsden NHS Foundation Trust

Fulham Road London United Kingdom SW3 6JJ

Study participating centre The Christie NHS Foundation Trust

Wilmslow Road Manchester United Kingdom M20 4BX

Study participating centre Airedale General Hospital

Airdale NHS Foundation Trust Skipton Road Steeton Keighley United Kingdom BD20 6TD

Study participating centre Kent and Canterbury Hospital

East Kent Hospitals University NHS Foundation Trust Ethelbert Road Canterbury United Kingdom CT1 3NG

Study participating centre The Royal Bournemouth Hospital

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

Study participating centre Royal Surrey NHS Foundation Trust

Egerton Road Guildford United Kingdom GU2 7XX

Study participating centre Lothian Health Board

Waverley Gate 2-4 Waterloo Place Edinburgh United Kingdom EH1 3EG

Study participating centre Yeovil District Hospital NHS Foundation Trust

Higher Kingston Yeovil United Kingdom BA21 4AT

Sponsor information

Organisation

University of Sussex

Sponsor details

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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 28/04/2025:

The researchers published the findings from this research in a high-impact peer-reviewed journal (Supportive Care of Cancer, April 2025; please see https://doi.org/10.1007/s00520-025-09440-7 and https://doi.org/10.1007/s00520-025-09444-3). A plain language summary of the findings will be sent to all study participants and published on the study website: https://shore-c.sussex.ac.uk/impactor.html. Additional documents are not currently available.

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: https://shore-c.sussex.ac.uk/impactor.html. Additional documents are not currently available.

Intention to publish date

26/04/2025

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?
HRA research summary			26/07/2023	No	No
Other publications	Qualitative analysis	26/04/2025	28/04/2025	Yes	No

<u>Results article</u> 26/04/2025 28/04/2025 Yes No