PRIMROSE Audit: A multicentre audit of care provided to patients with breast cancer involving the brain in the UK

Submission date	Recruitment status	Prospectively registered
13/08/2020	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2020	Completed	Results
Last Edited	Condition category	[] Individual participant data
07/10/2020	Cancer	Record updated in last year

Plain English summary of protocol

Background and study aims

Breast cancer is one of the most common cancers that can spread to the brain. We also know that there are different types of breast cancer and some of these spread more easily to the brain than others. Secondary cancer in the brain is usually deadly and reduces the quality of life in patients.

We wish to understand how breast cancer patients present with disease involving the brain, how they are managed across the UK nor what impact it has on their survival. With this knowledge, we will be able to improve the services and care for these patients.

Who can participate?

Records from patients aged 16 years or older, who suffer from breast cancer with central nervous system involvement.

What does the study involve?

The PRIMROSE audit will involve data that is routinely collected from patients diagnosed with breast cancer involving the brain between January 2020 and December 2021. The collected data will be anonymised before it can be used for research. The data will be collected by clinicians normally involved in the care of these patients.

What are the possible benefits and risks of participating? None

Where is the study run from? University of Liverpool

When is the study starting and how long is it expected to run for? January 2020 to July 2022

Who is funding the study? Daiichi-Sankyo (Japan)

Contact information

Type(s)

Public

Contact name

Prof Carlo Palmieri

ORCID ID

http://orcid.org/0000-0001-9496-2718

Contact details

Department of Molecular and Clinical Cancer Medicine
Institute of Translational Medicine
Sherrington Building, Ashton Street
University of Liverpool
Liverpool
United Kingdom
L69 3GE
+44 (0)151 706 3616
c.palmieri@liv.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

PRIMROSE Audit: A Prospective Multi-Centre Project to Assess the Presentation, Management, and Outcomes of Patients with CNS Disease Secondary to Breast Cancer

Acronym

PRIMROSE

Study objectives

To capture the local and regional variation in the presentation, diagnosis and management of patients with CNS disease secondary to breast cancer in the UK

Ethics approval required

Old ethics approval format

Ethics approval(s)

The PRIMROSE audit does not require research ethics committee (REC) review as it is an audit, and not a research project. This has been confirmed using the Health Research Authority (HRA) decision tools and as advised on the tools, we have sought further guidance from an HRA Approvals Specialist. Documents confirming the outcome of these are available on request. Local audit approvals will need to be obtained, with a supervising named consultant, if the unit lead is a trainee.

Study design

Prospective observational multi centre audit

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Central Nervous System disease secondary to breast cancer

Interventions

Patients' records will be reviewed to collect routine care data on demographic information, clinicopathological features and treatment of primary breast cancer, information relating to disease recurrence, prior cancer treatment for non-CNS metastatic disease (if applicable), surgical and radiotherapy treatment of CNS disease (if applicable), current anti-cancer treatment and concomitant medication, cancer-related outcomes

Intervention Type

Other

Primary outcome measure

Overall survival from initial diagnosis of CNS involvement secondary breast cancer measured using patient records at a single time point.

Secondary outcome measures

Measured at a single time point:

- 1. Number of cases of metastatic breast cancer involving the CNS presenting in UK centres per year measured using patient records
- 2. Current practice in UK centres regarding the diagnosis and management of CNS disease secondary to breast cancer in relation to national and international guidelines:
- 2.1. Prior cancer treatment for non-CNS metastatic disease
- 2.2. Surgical and radiotherapy treatment of CNS disease
- 2.3. Current anti-cancer treatment and concomitant medications
- 3. Outcomes of patients treated for CNS involvement secondary to breast cancer in UK centres:
- 3.1. Time to progression from surgery, radiotherapy or systemic therapy, defined as time from commencement of treatment for CNS disease to disease progression and site of progression
- 3.2. Overall survival measured as the time from diagnosis of recurrent disease until death of any cause
- 3.3. Cause of death: Progressive CNS disease versus progressive disease at other sites

Overall study start date

01/01/2020

Completion date

31/12/2022

Eligibility

Key inclusion criteria

- 1. ≥16 years of age
- 2. Histologically and/or cytologically confirmed breast cancer with CNS involvement, as defined as having one or more of the following:
- 2.1. Metastases to the brain parenchyma
- 2.2. Metastases to the leptomeninges
- 2.3. Paraneoplastic Neurological Disorders

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

As an audit/project, no formal sample size is set based on audit/project hypothesis. A target for the audit is to obtain 300 patients and given the poor prognosis of the target population it is a reasonable target that 100 events will be observed.

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/08/2020

Date of final enrolment

31/07/2022

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre Queen Elizabeth Hospital

Mindelsohn Way Edgbaston Birmingham United Kingdom B15 2WB

Study participating centre Southampton General Hospital

Tremona Road
Southampton
Hampshire
Southampton
United Kingdom
SO16 6YD

Study participating centre The Christie NHS Foundation Trust

Wilmslow Rd Manchester United Kingdom M20 4BX

Study participating centre University of Liverpool

Foundation Building Brownlow Hill Liverpool United Kingdom L69 3BX

Study participating centre Queen Elizabeth University Hospital

NHS Greater Glasgow and Clyde 1345 Govan Rd Glasgow United Kingdom G51 4TF

Study participating centre St. Mary's Hospital

Imperial College Healthcare NHS Trust Praed Street London United Kingdom W2 1NY

Sponsor information

Organisation

University of Liverpool

Sponsor details

1st Floor Block C Waterhouse Building 3 Brownlow Street Liverpool England United Kingdom L69 3GL +44 (0)151 794 2405 primrose@liverpool.ac.uk

Sponsor type

University/education

Website

http://www.liv.ac.uk/

ROR

https://ror.org/04xs57h96

Funder(s)

Funder type

Industry

Funder Name

Daiichi-Sankyo

Alternative Name(s)

Daiichi Sankyo Company, Limited, Daiichi Sankyo Co., Ltd.

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Japan

Results and Publications

Publication and dissemination plan

The results of the audit from different participating sites will be analysed together and published in the name of the audit as soon as possible, on behalf of all collaborators, maintaining participant confidentiality at all times.

Intention to publish date

01/03/2023

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date