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

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

Who is the main contact?
Professor Carlo Palmieri, c.palmieri@liv.ac.uk

Contact information

Type(s)
Public

Contact name
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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

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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