

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/10/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
Prof Carlo Palmieri

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Scotland

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

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

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