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PRIMROSE Tissue: collection and analysis of samples in breast cancer

Submission date
12/02/2021

Recruitment status
No longer recruiting

Registration date
21/05/2021

Overall study status
Completed

Last Edited
21/05/2021

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is the most common type of cancer in the UK.
PRIMROSE Tissue Study aims to collect and investigate archived tissue, excess CSF samples and related data (all collected as part of standard care) from patients with central nervous system disease secondary to breast cancer. This study does not involve additional procedures or interventions outside of standard care.

Who can participate?
Patients aged 16 years or above, with breast cancer

What does the study involve?
Patients will be informed of the study and consented to participate in PRIMROSE Tissue.
Following consent, arrangements will be made to request available archived FFPE tissue blocks of primary breast cancer tissue, non-cranial metastatic tissue or cranial metastatic tissue if available.
CSF samples will be collected only if the patient has been scheduled to undergo a CSF collection procedure as part of their standard care. In this case, an excess 10ml of CSF will be collected for the PRIMROSE Tissue study. Prior to CSF collection, 10ml blood will be collected for the study (which would not otherwise be collected).
The study can be carried out by trained clinical staff members, at sites with the appropriate and relevant facilities and this study does not involve experimental treatment or placebo treatment.

What are the possible benefits and risks of participating?
None

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
January 2021 to June 2025

Who is funding the study?
1. Daiichi-Sankyo (Japan)
2. Liverpool Experimental Cancer Medicine Centre (UK)

Who is the main contact?

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
287714

Central Portfolio Management System (CPMS)
47662

Study information

Scientific Title
Primrose tissue study: a collection and analysis of tissue and CSF samples from patients with CNS disease secondary to breast cancer

Study objectives
PRIMROSE Tissue Study aims to collect and investigate archived tissue, excess CSF samples and related data (all collected as part of standard care) from patients with central nervous system disease secondary to breast cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/01/2021, North West – Greater Manchester (GM) East (3rd Floor, Barlow House, 4 Minshull Street, M1 3DZ, UK; +44 (0)207 104 8009; gmeast.rec@hra.nhs.uk), ref: 20/NW/0451

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Breast Cancer

Interventions
Data and Tissue Collection After Enrolment
After written consent is given and after patient has been enrolled in the study the data should be entered into the database (from retrospective records sourced from medical records and patient medical notes). The research team at site should request available FFPE tissue blocks and send to the University of Liverpool GCP Laboratory according to the Laboratory Manual.

CSF Extraction Visit
This visit will only occur if the patient is undergoing a CSF extraction procedure as per standard care.

The following procedures will occur at this visit:
•Blood sample collection (1 x 10ml EDTA blood tube) – this should be collected immediately before the CSF extraction procedure
•Excess CSF sample extraction (1 x 10ml CSF tube and 1 x 3ml - 5ml CSF tube) – this should be carried out via Lumbar Puncture or Ommaya Reservoir aspiration or at standard care neurosurgery as per standard procedure (atraumatic needles should be used unless discussed with PI & CI). The CSF samples for the PRIMROSE Tissue study will be excess samples taken at the time of the standard care CSF extraction procedure.

Scan/Imaging Visit
This visit will only occur if the patient is booked in for a routine can as part of their standard care pathway. The Scan/Imaging Visit eCRF should be completed.

Disease Progression Visit
If patient comes in for a routine visit and there are no changes in disease or treatment, then there is no requirement to update eCRF.
In the event of patient disease progression, treatment changes or in the event of death, data and tissue will be collected as relevant.

Participant Discontinuation/Withdrawal
In consenting to the trial, participants agree to all trial activities including sample collection and data collection. Every effort should be made to facilitate the completion of these for every recruited participant. If it is not possible to complete these activities (or it is deemed inappropriate) the reasons why should be documented.

Patients may be withdrawn from the study for any of the following reasons:
-Patient (or their designated legal representative, where applicable) withdraws consent.
-Contraindications to collection procedures.
-Death
-Clinician-led
- Any change in the patient's condition which results in a contraindication to collection procedures or causes the patient to fall under the exclusion criteria.
- Any change in the patient's condition that justifies discontinuation of involvement in the clinician's opinion.

Data to be collected at the time of discontinuation includes date of discontinuation and reason for discontinuation.

If a patient wishes to withdraw, the value of existing samples should be explained, and permission sought to continue retaining and using these. Generally, samples will be retained unless it is specifically requested for them not to be.
Upon withdrawal, the LCTC and TMG should be informed in via eCRF and no further samples or data should be collected.

Permission will be sought to use all samples collected thus far in the case of withdrawal. However, patients have the right to request that any samples which have not yet already been used in research to be disposed of. If a patient explicitly states that this is their wish, then this will be recorded onto eCRF.

In some cases, it will be impossible to destroy the samples without affecting other samples as they will have been irreversibly linked to others (such as in cases of tissue microarrays being produced or plasma samples being pooled). In these cases, the sample itself will not be destroyed; however, information linking the sample to any patient identifiers will be destroyed, deleted or censored as appropriate to eliminate the link and make the sample unidentifiable.

End of Study
The end of the study is defined to be the date on which data for all participants is frozen and data entry privileges are withdrawn from the study database. The study may be closed prematurely by the Trial Steering Committee.

Intervention Type
Other

Primary outcome(s)
Clinical staff will be collecting information onto eCRFs (REDCap) at registration (1st or 2nd Visit), CSF Extraction Visit, Imaging/ Scan Visit, Disease Progression Visit:
1. Disease history and characteristics
2. Prior cancer therapy (top line)
3. Current anti-cancer treatment and concomitant medications Progression Details

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. 16 years of age or above
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
3. FFPE of biopsied or resected primary breast cancer, non-CNS metastasis and/ or brain metastasis is available or will be available.
4. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1.Unable to comply with study procedures or give informed consent

Date of first enrolment
01/06/2021

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre

The Walton Centre NHS Foundation Trust
Lower Lane
Liverpool
United Kingdom
L9 7LJ

Study participating centre
Wolfson Wohl Cancer Research Centre
Garscube Estate
Bearsden
United Kingdom
G61 1QH

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Southampton General Hospital
University of Southampton and University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal Liverpool University Hospital
Royal Liverpool University Hospitals NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street

Leeds
United Kingdom
LS9 7TF

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

Funder Name
Liverpool Experimental Cancer Medicine Centre

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version v2.0	20/10/2020	21/05/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes