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Clinical application of drug screening in circulating tumor cells in patients with breast cancers

Submission date 04/08/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/08/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/08/2024	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is the leading cancer death for women worldwide, and the mortality rate is still high although several clinical drugs have been developed within this decade. Therapeutic failure results in tumor recurrence and metastasis is still a major challenge for clinicians and researchers. Circulating tumor cells (CTCs) are rare cells (1 CTCs/106 hematopoietic cells) in the peripheral blood that usually remain undetected by clinically used high-resolution imaging technologies. However, drug screening of CTCs for therapeutic purposes remains to be explored. This study aims to investigate the clinical impact of CTCs either in drug screening or survival of patients with breast cancer.

Who can participate?
Female newly diagnosed primary locally advanced breast cancer patients enrolled in Linkou Chang Gung Memorial Hospital

What does the study involve?
Participants were scheduled to receive either systemic treatment including chemotherapy, immunotherapy, target therapy or endocrine therapy for their tumors for CTC enumeration. A sample of primary tumor tissue was also taken for an immunohistochemistry study for correlation of the result of CTCs including the relationship of immune cells and tumor cells. The outcome of the patients will be evaluated including the clinical and pathological response of the treatment, time to progression and the follow-up time will be up to 3 years.

What are the possible benefits and risks of participating?
The study results do not influence the treatment option, so there is no direct benefit for clinical outcome but the study will provide prognostic information from the disease.
This is an observational study that does not contain any risk to the participants.

Where is the study run from?
Linkou Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
March 2020 to July 2023

Who is funding the study?
Chang Gung Medical Foundation (Taiwan)

Who is the main contact?
Hsu-Huan Chou (Principal Investigator), b9002009@cgmh.org.tw

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Clinical application of drug screening in circulating tumor cells and exploring the impact of tumor microenvironment on the drug responses in patients with breast cancers

Study objectives

The prognostic value of circulating tumor cells (CTCs) is well established in breast cancer treatment, however, the drug screening of CTCs for therapeutic purposes remains to be explored. This study aims to investigate the clinical impact of CTCs in drug screening for the survival of patients with breast cancer.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/03/2020, Chang Gung Medical Foundation Institutional Review Board (199, Tung Hwa North Road, Taipei city, 10507, Taiwan; +886-3-3196200 #3703; irb1@cgmh.org.tw), ref: 202000120A3

Study design
Single-center prospective observational trial

Primary study design
Observational

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Clinical application of drug screening in circulating tumor cells in patients with breast cancers

Interventions
This study will investigate the clinical impact of circulating tumor cells (CTCs) in drug screening for the survival of patients with breast cancer. While the predictive value of CTCs is well established in breast cancer treatment, their role in drug screening for therapeutic purposes remains to be explored.

This study is a prospective observational cohort study involving a single study group, without an intervention or control group for comparison. Blood samples will be collected both before and after treatment for research purposes.

It is important to note that no intervention will be conducted throughout the study, and the results of the in vitro tests will not influence the treatment decisions for the patients. The study period will extend from enrollment to the end of medical data participation, encompassing the total duration of observation and follow-up.

Intervention Type
Other

Primary outcome(s)
Correlation between anti-cancer drug tests and patient's clinical outcome measured using data collected from patient medical records as the evaluation of drug response between baseline and 3 to 6 months after treatment

Key secondary outcome(s))

The prognostic and predictive role of the count of circulating tumor cells (CTCs) measured using a fluorescence microscope to count CTCs and CTC-white blood cells (WBCs) at baseline, 3 to 6 months after treatment

Completion date
31/07/2023

Eligibility

Key inclusion criteria
Newly diagnosed primary locally advanced female breast cancer patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
Female

Total final enrolment
34

Key exclusion criteria
1. Participants undergoing primary surgery
2. Without informed consent

Date of first enrolment
05/03/2020

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang Gung Memorial Hospital, Linkou
No.5, Fuxing St., Guishan Dist.
Taoyuan City
Taiwan
333

Sponsor information

Organisation
Linkou Chang Gung Memorial Hospital

ROR
https://ror.org/02dnn6q67

Funder(s)

Funder type
Charity

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes