

Tamoxifen-related endocrine symptoms in Chinese patients with breast cancer

Submission date 25/09/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/08/2022	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 the most prevalent cancer in women in Hong Kong and worldwide. After treatment such as surgery and chemotherapy, disease recurrence remains a significant concern. Nowadays, a common practice to prevent recurrence is to have women on adjuvant tamoxifen, a hormonal therapy, for 5 years. The relapse rate at 5 years for patients who adhere to adjuvant tamoxifen is significantly lower than for those women who discontinue the drug. However, among patients who receive adjuvant tamoxifen treatment, individual responses are highly variable. These variable responses include the type, frequency and severity of endocrine symptoms and reduced tamoxifen adherence, which ultimately affect the cancer recurrence rate. Polymorphisms (genetic variations) in some genes involved in the metabolism of tamoxifen are likely to influence these detrimental responses to tamoxifen. This study aims to characterize the genetic polymorphisms of tamoxifen metabolism-associated genes in Chinese women with breast cancer and to explore the inter-relationships between genetic polymorphisms, endocrine symptoms, and adherence to tamoxifen that could affect the effectiveness of treatment.

Who can participate?

Chinese women with breast cancer treated with surgery and chemotherapy and started on tamoxifen within the past month

What does the study involve?

A questionnaire consisting of demographics, health status details, assessment of endocrine symptoms and drug adherence is completed at the start of the study and after 3, 6, 9 and 12, 15, and 18 months by phone interview. At 12 and 18 months, information on breast cancer recurrence is collected. A saliva sample is also collected from the participants at the start of the study to test for genetic polymorphisms. Participants keep a medication log book to record their intake of tamoxifen, supplements, Chinese herbal medicine, and other medications on a daily basis. The surveys are completed anonymously.

What are the possible benefits and risks of participating?

There are no risks and benefits expected from the study.

Where is the study run from?

Chinese University of Hong Kong and Prince of Wales Hospital (Hong Kong)

When is the study starting and how long is it expected to run for?

November 2016 to August 2021

Who is funding the study?

Chinese University of Hong Kong (Hong Kong)

Who is the main contact?

Prof. Carmen Wing Han Chan

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Contact information

Type(s)

Scientific

Contact name

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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

Identification of predictive biomarkers for tamoxifen-related endocrine symptoms and drug adherence based on genetic polymorphisms in Chinese patients with breast cancer: a prospective pilot study

Study objectives

1. There is a relationship between the severity of tamoxifen-induced endocrine symptoms and allelic variations in tamoxifen metabolism-related genes
2. Patients with more severe endocrine symptoms (psychological, vasomotor, somatic or sexual) are less likely to adhere to tamoxifen

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/12/2016, The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong; Tel: +852 (0)35053935; Email: crec@cuhk.edu.hk), Approval #2016.554

Study design

Prospective cohort study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Breast cancer

Interventions

This prospective cohort study will recruit patients from the Department of Clinical Oncology in Prince of Wales Hospital in Hong Kong. Self-reported endocrine symptoms and the saliva of patients will be collected at enrolment. At 3, 6, 9, 12, 15, 18 months after enrolment, data on symptoms and drug adherence will be collected by phone interview using the same measures. Data collection will stop at 18 months because symptoms of tamoxifen therapy appear early and are worst during the first 12 months after the initiation of treatment. Patients' saliva will be collected during enrolment for the single nucleotide polymorphism (SNP) evaluation of genes associated with drug metabolism enzymes and transporters.

Intervention Type

Other

Primary outcome(s)

Endocrine symptoms measured using the Greene Climacteric Scale (GCS) and the Functional Assessment of Cancer Therapy-Endocrine subscale (FACT-ES) questionnaire (version 4) at enrolment, 3, 6, 9, 12, 15 and 18 months

Key secondary outcome(s)

Drug adherence measured using the Modified Medication Adherence Report Scale (MMARS) and the Medication Possession Ratio (MRP) at 3, 6, 9, 12, 15 and 18 months

Completion date

31/08/2021

Eligibility

Key inclusion criteria

1. Chinese women with histologically confirmed estrogen receptor-positive, stage I–III, primary invasive breast cancer
2. Treated with definitive surgery and/or chemotherapy and started on tamoxifen (20 mg daily) within the past month

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Patients with other primary malignancies within the last 5 years
2. Patients who are pregnant or are planning to become pregnant, lactating
3. Treated with investigational drugs within the 4 weeks prior to enrolment
4. Not able to provide informed consent

Date of first enrolment

23/12/2016

Date of final enrolment

31/08/2020

Locations

Countries of recruitment

Hong Kong

Study participating centre

The Chinese University of Hong Kong

Department of Clinical Oncology

Prince of Wales Hospital, Shatin, New Territories

Hong Kong

Hong Kong

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Sponsor information

Organisation

The Chinese University of Hong Kong

ROR

<https://ror.org/00t33hh48>

Funder(s)

Funder type

University/education

Funder Name

Chinese University of Hong Kong

Alternative Name(s)

The Chinese University of Hong Kong, , , Hēunggóng Jūngmàhn Daaihohk, CUHK,

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as the researchers planned to have the data for research and publication use only. They will keep the dataset in their computer with encryption.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/02/2020	19/08/2022	Yes	No