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Tamoxifen-related endocrine symptoms in Chinese patients with breast cancer

Submission date 25/09/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 27/09/2019	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/08/2022	**Condition category** Cancer	[_] Individual participant data [_] 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 womenwith 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?
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Contact information

Type(s)
Scientific

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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
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
01/11/2016

Completion date
31/08/2021

Eligibility

Key inclusion criteria
1. Chinese womenwith 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

Age group
Adult

Sex
Female

Target number of participants
30

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
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Sponsor information

Organisation
The Chinese University of Hong Kong

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Sponsor type
University/education

Website
http://www.nur.cuhk.edu.hk/home-page/

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, , CUHK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Hong Kong

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journals at 6-12 months after the data collection was ended.

Intention to publish date
31/08/2022

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