

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of increasing tamoxifen dose based on CYP2D6 genotype on the endoxifen concentration and adverse events in breast cancer patients of Isfahan city

Protocol summary

Summary

Breast cancer is the most common cancer among women. Many of these patients are ER+ and use tamoxifen to treat. However, 50-30% of patients show resistance to tamoxifen and relapse. Of the most important reasons of drug resistance is impaired metabolism of tamoxifen. CYP2D6, the most important enzyme involved in the metabolism of tamoxifen, has different alleles with different activities. PM and IM are null and decreased alleles respectively and are less active than EM (normal allele). Many studies have shown a strong association between CYP2D6 genotype and results of treatment with tamoxifen. Some studies have used CYP2D6 genotyping to determine the dose of tamoxifen. The limitations of the studies in this field was using the same dose of tamoxifen for different genotypes of IM, PM and EM alleles. While people with different genotypes have different amounts of drug metabolism. To address the limitations of these studies, it is designed to first, score the patients according to CYP2D6 genotype (Scoring), and then the dose can be determined exactly based on the patient's genotype. Patients with genotypes EM/EM, EM/IM use 20mg /day, genotypes EM/PM, IM/IM use 30mg/day and genotypes IM/PM, PM/PM use 40mg/day of tamoxifen. Finally after 4 months, the relationship between increasing dose of tamoxifen and endoxifen concentration and the side effects will be studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082323734N1**

Registration date: **2015-10-12, 1394/07/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-12, 1394/07/20

Registrant information

Name

Zahra Khalaj

Name of organization / entity

Isfahan University of Medical Sciences

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Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of increasing tamoxifen dose based on CYP2D6 genotype on the endoxifen concentration and adverse events in breast cancer patients of Isfahan city

Public title

Evaluation of the effects of increasing tamoxifen dose on the treatment process in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Women were eligible if they were on tamoxifen 20 mg daily for at least 4 months; nonpregnant; had normal kidney, liver, and bone marrow function. Patients were excluded if they had a concurrent medication therapy with medications known to inhibit CYP2D6.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences , Hezarjarib street

City

Isfahan

Postal code

8174673461

Approval date

2015-08-30, 1394/06/08

Ethics committee reference number

IR.MUI.REC.1394.3.446

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Endoxifen

Timepoint

After using 20mg/day tamoxifen for at least 4 month, 4 month after intervention

Method of measurement

Liquid Chromatography tandem Mass Spectrometry (LC-MS/MS)

Secondary outcomes

1

Description

Side effects

Timepoint

Four months after intervention

Method of measurement

Questionnaires

Intervention groups

1

Description

Intervention group 1: tamoxifen, 30mg oral, twice a day

Category

Treatment - Drugs

2

Description

Intervention group 2: tamoxifen, 40mg oral, twice a day

Category

Treatment - Drugs

3

Description

Control group: tamoxifen, 20mg oral, once a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Center for breast Cancer Prevention

Full name of responsible person

Dr. Fariborse Mokarian

Street address

Seyedoshohada hosbital, Emamreza clinic, Research
Center for breast Cancer Prevention

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Salehi

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Isfahan University of Medical Sciences, Hezarjarib
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City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Zahra Khalaj

Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty