

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Oct 2021

### 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3630 8467

###### Email address

zkhalaj@resident.mui.ac.ir

##### 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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**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**

PhD student

**Other areas of specialty/work****Street address**

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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*