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 Siences

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 Siences

Street address
Isfahan University of Medical Siences , 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 Siences
Full name of responsible person
Dr. Mansour Salehi
Street address
Isfahan University of Medical Siences, Hezarjarib street
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 Siences
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 Siences
Full name of responsible person
Zahra Khalaj
Position
PhD student
Other areas of specialty/work
Street address
Isfahan University of Medical Siences, Hezarjarib street
City
Isfahan
Postal code
8174673461
Phone
+98 31 3630 8467
Fax
Email
zkhalaj@resident.mui.ac.ir; z_kh240@yahoo.com; zkh240@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Siences
Full name of responsible person
Zahra Khalaj
Position
PhD student
Other areas of specialty/work
Street address
Isfahan University of Medical Siences, Hezarjarib street
City
Isfahan
Postal code
8174673461
Phone
+98 31 3630 8467
Fax
Email
zkhalaj@resident.mui.ac.ir; z_kh240@yahoo.com; zkh240@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Siences
Full name of responsible person
Zohreh Baratieh
Position
PhD student
Other areas of specialty/work
Street address
Isfahan University of Medical Siences, Hezarjarib street
City
Isfahan
Postal code
8174673461
Phone
Fax
Email
zbaratieh@resident.ac.ir
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