

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Assessment of the effect of hypothyroidism treatment with levothyroxine on the improvement of benign breast disorders in women attending the breast clinic of Arash Womens Hospital.

Protocol summary

Summary

The aim of this study is to determine the effect of hypothyroidism treatment with levothyroxine on benign breast disorders in women attending the breast clinic of Arash Women's Hospital .This double blind ,non randomized study to be conducted with control group in one center .Inclusion criteria include Women with fibrocystic disease , mild and moderate mastalgia , nipple discharge Exclusion criteria include :The patient considered for surgical intervention; pregnant women , women taking oral contraception pill , history of breast cancer ;high levels of prolactin , history of hyperthyroidism or hypothyroidism. Among women with benign breast disorder attending the breast clinic of Arash Women's Hospital, 31 women with hypothyroidism (case group)and 31euthyroidism women (control group)will enrolled in this study.Case group are treated with levothyroxine for three months.Before and after intervention, breast pain intensity, intensity of fibrocystic disorders and nipple discharge are evaluated by ultrasound and clinical examination of breast and visual analog scale.Then we will evaluate and compare this finding in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206264329N3**
Registration date: **2012-08-30, 1391/06/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-30, 1391/06/09

Registrant information

Name

Sadaf Alipour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of hypothyroidism treatment with levothyroxine on the improvement of benign breast disorders in women attending the breast clinic of Arash Womens Hospital.

Public title

The effect of hypothyroidism treatment with levothyroxine on improvement of benign breast disorders

Purpose

Screening

Inclusion/Exclusion criteria

Women with fibrocystic disease;Mild and moderate mastalgia ; nipple discharge : Inclusion criteria. The patient considered for surgical intervention; Pregnant women ; Women taking oral contraception pill ;history of breast cancer ;High levels of Prolactin ;History of hyperthyroidism or hypothyroidism: Exclusion criteria

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 62

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Deputy of Research ,Tehran University of Medical Science,

Street address

Qods St, Keshavarz Blvd.

City

Tehran

Postal code

1417653761

Approval date

2012-08-01, 1391/05/11

Ethics committee reference number

60338

Health conditions studied**1****Description of health condition studied**

Fibrocystic mastopathy

ICD-10 code

N60/1

ICD-10 code description

Diffuse cystic mastopathy

2**Description of health condition studied**

Mastodynia

ICD-10 code

N64/4

ICD-10 code description

Mastodynia

3**Description of health condition studied**

Nipple discharge

ICD-10 code

N64/5

ICD-10 code description

Other signs and symptoms in breast/nipple discharge

Primary outcomes**1****Description**

intensity of benign breast disorders

Timepoint

Before and 3 months after intervention

Method of measurement

Clinical exam.Ultrasound .Visual Analog Scale

Secondary outcomes

empty

Intervention groups**1****Description**

there is no intervention in the control group.

Category

N/A

2**Description**

intervention in the case group is administration of tablet levothyroxine with 50 Micrograms initial dose , for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash Women 's Hospital

Full name of responsible person

Sadaf Alipour.Assistant of professor of surgery

Street address

Arash Women 's Hospital, Rashid Ave, Resalat

Highway, Tehranparse,Tehran.Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences,Deputy of Research

Full name of responsible person
Akbar Fotohi

Street address
Qods St,Keshavarse Blvd

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences,Deputy of Research

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
Tehran University of Medical Sciences

Full name of responsible person
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Position
Assistant of professor of Surgery

Other areas of specialty/work

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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