

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of the effect of vitamin B6 on reducing the number and size of the breast cysts and rate of recurrence after aspiration in Amiralmomen Hospital, Semnan

Protocol summary

Summary

In this double blind randomized clinical trial study, reduction of the size and number of the breast cysts after consumption of Vitamin B6 is evaluated. In patient with palpable cyst, at first the cyst is aspirated. These patients and patients with non-palpable cysts will be divided in two groups; in case group 150 mg Vitamin B6 BD and in control group placebo will be used for two months. In all patients cysts size and number will be recorded before and after the trial according to sonographic findings. At the end findings in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102615162N1**
Registration date: **2013-12-21, 1392/09/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-21, 1392/09/30

Registrant information

Name

Jafar Alavy Toussy

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1445 7244

Email address

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin B6 on reducing the number and size of the breast cysts and rate of recurrence after aspiration in Amiralmomen Hospital, Semnan

Public title

Evaluation of the effect of vitamin B6 on reducing the number and size of the breast cysts and rate of recurrence after aspiration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Palpable and non-palpable breast cysts (detected in sonography); Palpable breast cysts which evacuated completely after aspiration; 3- Patients in reproductive ages Exclusion criteria: Complex breast cysts according to sonographic findings; Bloody fluid in aspiration of the breast cyst; Cysts that not completely resolved after aspiration; Cysts with mammographic suspicious findings; patients that consume OCP

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Basij Boulevard

City

Semnan

Postal code

Approval date

2013-06-11, 1392/03/21

Ethics committee reference number

92/16/3682

Health conditions studied

1

Description of health condition studied

Solitary cyst of breast

ICD-10 code

N60.0

ICD-10 code description

Solitary cyst of breast

2

Description of health condition studied

Diffuse cystic mastopathy

ICD-10 code

N60.1

ICD-10 code description

Diffuse cystic mastopathy

Primary outcomes

1

Description

Size of breast cysts

Timepoint

Beginning of study, End of study

Method of measurement

Breast sonography

2

Description

Number of breast cysts

Timepoint

Beginning of study, End of Study

Method of measurement

Breast sonography

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group, Vitamin B6 150 mg BD for 2 months (powdered tablet in capsule, produced by Iran Hormone company).

Category

Treatment - Drugs

2

Description

In control group placebo (containing sugar in the same capsules) prescribed as the case group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery clinic of Amir-al-Momenin Hospital

Full name of responsible person

Dr Setareh Soltany

Street address

Surgery department, Koosar Hospital, Shahrak-e Golestan

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Rahbar

Street address

Basij Boulevard, Moavenet-e Tahghigat

City

Semnan

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

Yes

Title of funding source

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Dr Jafar Alavy Toussy

Position

Pathologist / Lecturer

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

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Full name of responsible person

Dr Setareh Soltany

Position

Surgeon / Associate professor

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

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Full name of responsible person

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Web page address

<http://www.toussysoftware.com>

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