

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Effect of thiamine tablet (B 1) on general health and treatment success in infertile women with polycystic ovary syndrom

Protocol summary

Summary

My objective is to test the Effect of thiamine tablet (B 1) on general health and treatment success in infertile women with polycystic ovary syndrome . 64 women who have polycystic ovary syndrome will be randomly divided into 2 group. After completing the data for each patient blood samples taken at this stage and b-HCG hormone tests and the number of oocytes and their status will be determined. One of them will use 300mg tab tiamin . the other group will use placebo tablet daily. After the treatment period, again from all the people who are excluded from the study is not the General Health Questionnaire (GHQ) will be completed for evaluation indicators of treatment success (the number of follicles, the quality of follicles, number of oocytes) and a test of B-HCG as the positive therapeutic response will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510266917N3**

Registration date: **2016-05-01, 1395/02/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-01, 1395/02/12

Registrant information

Name

Leila Amini

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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l-amini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

1- nursing and midwifery school, Iran University of Medical Science 2- sareem specialized hospital of gynecology

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of thiamine tablet (B 1) on general health and treatment success in infertile women with polycystic ovary syndrom

Public title

Effect of thiamine tablet (B 1) on general health and treatment success in infertile women with polycystic ovary syndrom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with PCOs according to Rotterdam criteria; age 18-40 years be agree with study; not use alcohol; non usage psychological drugs; non addict or a history of addiction; without basic illness ; non usage of B1 last month; not using complimentary drug last month; at-last 3 period treatment of infertility exclusion criteria: not agree with continue the study;

appears allergic symptoms; incorrect drug usage;
discontinue treatment of infertility

Age

From **76 years** old to **54 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomized study using Blocking.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Iran University of Medical Science

Street address

Tehran, Hemat high way, Iran University of medical science

City

Tehran

Postal code

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number

IR.IUMS.RREC.1394_26840

Health conditions studied

1

Description of health condition studied

polycystic ovarian syndrom

ICD-10 code

E28.2

ICD-10 code description

2

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Primary outcomes

1

Description

General health

Timepoint

before and after of intervention

Method of measurement

standard questionnairey

2

Description

Success treatment

Timepoint

before and after of intervention

Method of measurement

positive pregnancy test

Secondary outcomes

1

Description

B-HCG

Timepoint

Before and after of experiment

Method of measurement

hormone assay

Intervention groups

1

Description

Intervention group: treated with 300 mg vitamin B1 tablets product HAKIM Pharmaceutical Company once in the morning for a period of 4 weeks during experimental

Category

Treatment - Drugs

2

Description

product Control group: treated with placebo tablets 300 mg product HAKIM Pharmaceutical Company during experimental

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

sarem hospital

Full name of responsible person

Mahtab Moti

Street address**City**

tehran

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

Vice chencelor for research, Iran Nursing and Midwifry School, Iran University of Medical Science

Full name of responsible person

masoumeh abdoli

Street address

Hemat St.

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tehran

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

Yes

Title of funding source

Vice chencelor for research, Iran Nursing and Midwifry School, Iran University of Medical Science

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**

Iran Nursing and Midwifry School

Full name of responsible person

mahtab moti

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MSc student

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PhD candidate

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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*