

# 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)

##### Phone

+98 21 3316 6574

##### Email address

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.

**City**

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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mahtab\_moti@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran Nursin and Midwifery School

**Full name of responsible person**

Leila Amini

**Position**

PhD candidate

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Iran Nursin and Midwifery School

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MSc

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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*