

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The efficacy of Levothyroxin in euthyroid patient suffering from dysfunctional uterine bleeding

Protocol summary

Summary

Aim of research is the study of Levothyroxin efficacy in euthyroid patient suffering from dysfunctional uterine bleeding. The method of research is randomized triple blind placebo controlled clinical trial. Study population are female patients suffering from dysfunctional uterine bleeding referred to Taleghani Hospital and Amiralmomenin Hospitals Arak, Iran. Inclusion criteria: age range 35 to 55 years and dysfunctional uterine bleeding. Exclusion criteria: pregnancy; diabetes mellitus; hyperprolactinemia; coagulopathy; uterine fibroma; endocervical and endometrial polyp; atypical hyperplasia or adenocarcinoma; ovarian cyst; ovarian mass; hormonotherapy; thyroid dysfunction and contraindication of oral contraceptive pills. 120 patients are randomly divided in two groups (intervention and control). Both groups receive oral contraceptive pill for 3 months. In addition to oral contraceptive intervention group receive Levothyroxin 50 microgram/day and controlled group receives placebo. The time of intervention is 3 months from the start date. Primary outcome is change in severity of uterine bleeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303294686N2**
Registration date: **2013-04-09, 1392/01/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-09, 1392/01/20

Registrant information

Name

Mehri Jamilian

Name of organization / entity

School of Medicine, Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Dr.Saeed changizi Ashtiyani (Arak University of Medical Sciences, vice president of education and research)

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Levothyroxin in euthyroid patient suffering from dysfunctional uterine bleeding

Public title

The efficacy of Levothyroxin in euthyroid patient suffering from dysfunctional uterine bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age range 35 to 55 years and dysfunctional uterine bleeding. Exclusion criteria: pregnancy; diabetes mellitus; hyperprolactinemia; coagulopathy; uterine fibroma; endocervical and

endometrial polyp; atypical hyperplasia or adenocarcinoma; ovarian cyst; ovarian mass; hormone therapy; thyroid dysfunction and contraindication of oral contraceptive pills .

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

basij square

City

Arak

Postal code

3819691187

Approval date

2012-11-21, 1391/09/01

Ethics committee reference number

4-139-91

Health conditions studied

1

Description of health condition studied

Dysfunctional uterine bleeding

ICD-10 code

N93

ICD-10 code description

Other specified abnormal uterine and vaginal bleeding

Primary outcomes

1

Description

Severity of uterine bleeding

Timepoint

Before intervention and at the end of intervention

Method of measurement

Clinical examination

Secondary outcomes

1

Description

Drug side effects

Timepoint

Before intervention and every 1 month

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group receive oral contraceptive pill plus Levothyroxin 50 microgram /day for 3 months .

Category

Treatment - Drugs

2

Description

Controlled group receive oral contraceptive pill plus placebo for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital -Amiralmomenin Hospital

Full name of responsible person

Mehri Jamilian

Street address

Taleghani Hospital

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University Medical of Sciences

Full name of responsible person
Dr. Ashtiany
Street address
Basij square
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University Medical of 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

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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