Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of Medroxyprogestrone acetate and Tranexamic acid in women with menorrhagia

Protocol summary

Summary

This is a double blind, controlled trial to explore the effects of Medroxyprogestrone acetate and Tranexamic acid on menstrual blood loss volume, Quality of life, and duration of menstrual cycle. 76 women, aged 20-45 years old, with regular cycles who complain of heavy menstrual bleeding are randomly allocated to receive Tranexamic, 500mg Q6h, days 1-5 of menstrual cycle, or Medroxyprogestrone acetate , 5mg Q12h, days 5-26 of menstrual cycles. The menstrual blood volume, quality of life, and side effects of drugs are measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802131641N3**
Registration date: **2010-05-29, 1389/03/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-05-29, 1389/03/08

Registrant information

Name
Azita Goshtasebi
Name of organization / entity
Tarbiat Modares University
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Recruitment status

Recruitment complete

Funding source

Research office of Tarbiat Modares University

Expected recruitment start date

2009-03-02, 1387/12/12

Expected recruitment end date

2010-06-21, 1389/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Medroxyprogestrone acetate and Tranexamic acid in women with menorrhagia

Public title

Clinical trial of Medroxyprogestrone acetate and Tranexamic acid in women with menorrhagia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 20-45 years old, Regular menses, Heavy menstrual bleeding in several cycles, BMI 19-29
Exclusion criteria: Irregular menses or intra menstrual bleeding, Existence of uterine fibroids>3cm or other pathologic or iatrogenic causes for abnormal bleeding, Any systemic disease affecting menstrual bleeding, Using hormonal drugs (includes OCPs) or other drugs which influence on menstrual bleeding, Having intra uterine device, Pregnancy, Anemia (Hb<11), any therapeutic or preventive regimes for iron deficiency anemia

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Department Ethics Committee of Tarbiat Modares University

Street address

Medical building1, Tarbiat Modares university, Nasr bridge,

City

Tehran

Postal code

14117-13116

Approval date

empty

Ethics committee reference number

15082873

Health conditions studied

1

Description of health condition studied

menorrhagia

ICD-10 code

N92.0

ICD-10 code description

Excessive and frequent menstruation with regular cycle

Primary outcomes

1

Description

menstrual blood loss

Timepoint

one, two and three cycles after intervention

Method of measurement

by using pictorial blood loss assessment chart

Secondary outcomes

1

Description

quality of life

Timepoint

before and after intervention

Method of measurement

by using Aberdeen menorrhagia Questionnaire

Intervention groups

1

Description

Tranexamic acid, 500mg, Q6h, days1-5 of menstrual cycle.

Category

Treatment - Drugs

2

Description

Medroxyprogestrone asetate, 5 mg, Q12h, days 5-26 menstrual cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran East Health Center

Full name of responsible person

Somayeh Moukhah

Street address

No. 91, Ardestani Ave., 17 Shahrivar Jonoobi Ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Asisstant of Tarbiat Modares University

Full name of responsible person

Dr Azita Goshtasebi

Street address

Tarbiat Modares University, Nasr bridge,

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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

Research Asisstant of Tarbiat Modares University

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

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Position

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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