

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of hormone therapy on bone mass density in amenorrhea/oligomenorrhea female athletes

Protocol summary

Summary

The aim of this study is to evaluate the effect of contraceptive therapy on bone mineral density, cardiovascular factors, and lipid profiles of female athletes who are experienced amenorrhea/oligomenorrhea. Thirty elite female athletes competing in national teams or Tehran's medalists in 34 sport fields who have reported amenorrhea/oligomenorrhea participate in this study (based on Inclusion and exclusion criteria). Half of the participants take oral contraceptive (30 mug ethinyl estradiol and 150 mug levonorgestrel) for nine months. Bone mineral density, cardiovascular factors and lipid profiles will be measured before and after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904024251N1**

Registration date: **2010-09-12, 1389/06/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-09-12, 1389/06/21

Registrant information

Name

Haleh Dadgostar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research committee of Iran University of Medical sciences

Expected recruitment start date

2010-07-06, 1389/04/15

Expected recruitment end date

2011-04-04, 1390/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of hormone therapy on bone mass density in amenorrhea/oligomenorrhea female athletes

Public title

The effects of hormone therapy on bone mass density in amenorrhea/oligomenorrhea female athletes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Iranian elite female athletes, presence of amenorrhea/oligomenorrhea Exclusion criteria: regular menstruation pattern before beginning of the study, cessation of exercise, using hormonal medication, calcium supplement, or thyroid hormone

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Committee of Iran University of medical science.

Street address

Cross Expway of Shahid Hemmat & Shahid Chamran.

City

Tehran

Postal code

15875-6171

Approval date

2010-06-07, 1389/03/17

Ethics committee reference number

172994

Health conditions studied

1

Description of health condition studied

Amenorrhea/Oligomenorrhea

ICD-10 code

N91

ICD-10 code description

Absent, scanty and rare menstruation

Primary outcomes

1

Description

Menstrual pattern among athletes

Timepoint

Every month for nine months

Method of measurement

through coming to clinic or phone or fax or email for athletes who do not live in Tehran

2

Description

Bone mineral density

Timepoint

Baseline and after nine months

Method of measurement

Bone Densitometry maschine (HOLOGIC)

Secondary outcomes

1

Description

weight

Timepoint

Baseline and after nine monthsafter

Method of measurement

in kilograms by Balance

2

Description

Heart Rate and Blood pressure in supune position

Timepoint

Baseline and after nine monthsafter

Method of measurement

stethoscope and Blood pressure cuff

3

Description

waist circumference

Timepoint

Baseline and after nine monthsafter

Method of measurement

in centimeters by Tape

4

Description

Height

Timepoint

Baseline and after nine monthsafter

Method of measurement

in centimeters by Tape

5

Description

Lipid profile include (Total cholestrol (LDL, HDL), TG, Apo a and Apo b)

Timepoint

Baseline and after nine monthsafter

Method of measurement

Blood sample

6

Description

cardiovascular factors (hemocystein and Fibrinogen)

Timepoint

Baseline and after nine monthsafter

Method of measurement

Blood sample

Intervention groups1**Description**

oral contraceptive (30 mug ethinyl estradiol and 150 mug levonorgestrel) for 9 months

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Rassole Akram Hospital

Full name of responsible person

Haleh Dadgostar MD

Street address

Sattarkhan St. Shahr-Ara St.

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Research committee of Iran University of Medical Sciences

Full name of responsible person

Mazyar Moradi Lakeh MD

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City

Tehran

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

Yes

Title of funding source

Research committee of Iran 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**

Iran University Of Medical Sciences

Full name of responsible person

Haleh Dadgostar MD

Position

Assistant professor

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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