Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparative of the effect of Combined oral contraceptive pills (COCs) and vitamin D - COCs on Ovulatory dysfunction bleeding (AUB-O) in reproductive age women : A triple blind randomized controlled clinical trial

Protocol summary

Study aim
Comparison of the effect of combined oral contraceptives (COCs) and vitamin D-C0Cs on ovulatory dysfunction bleeding in women of reproductive age

Design
Controlled clinical trial, phase 3, with two parallel groups, three blinds

Settings and conduct
This study will be performed in Kosar Hospital in Qazvin. A member of the non-research team involved in the selection of samples will determine the random allocation sequence using a computer program. Closed opaque envelopes will be used numbered in order to conceal the allocation. Eligible individuals will be randomly assigned to two groups using block sizes of 4 and 6 blocks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18-45 years old women Have at least 2-3 months of history of excessive, prolonged and irregular bleeding Have a phone number to follow up. Exclusion criteria: Pregnancy Having any cervical abnormality Having any kind of severe psychological stress Having systemic diseases Taking vitamin D supplements for the past three months. Taking drugs that affect the menstrual cycle Having Premenstrual Syndrome Contraindications to the use of combined contraceptive pills

Intervention groups
In COCs group: capsul LD (containing 30 micrograms ethinyl estradiol and 150 micrograms levonorgestrel), 21 pieces with 9 placebo capsules for use In each cycle and in the COCs _ vitamin D group, combination capsules containing vitamin D (1000 units of calciferol) and LD (containing 30 micrograms of ethinyl estradiol and 150 micrograms of levonorgestrel) in the amount of 21 and then 9 vitamin D capsules a day, they will be placed in the same packets in three separate cycles for consumption

Main outcome variables
Amount of volume and days of menstrual bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110606006709N22**
Registration date: **2021-02-24, 1399/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-24, 1399/12/06**
Update count: **0**

Registration date
2021-02-24, 1399/12/06

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-05-31, 1400/03/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative of the effect of Combined oral contraceptive pills (COCs) and vitamin D - COCs on Ovulatory dysfunction bleeding (AUB-O) in reproductive age women : A triple blind randomized controlled clinical trial

Public title
Comparison of the effect of COCs and vitamin D-COCs on ovulatory dysfunction Bleeding in reproductive age women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women 18-45 years old Have at least 2-3 months of history of excessive, long and irregular bleeding (lack of regular cycle 28-35, bleeding more than 7 days or heavy) Have a phone number to follow up.
Exclusion criteria:
Pregnancy Any cervical abnormality including cervical cancer, infection, trauma or polyp and uterine causes including: leiomyoma, infection, polyp, endometrial hyperplasia, endometrial neoplasia, cancer or the presence of a foreign body based on the patient's statement and medical records. Having any kind of severe psychological stress such as: separation of parents, death of first-degree family members, etc. in the last 6 months. Having any kind of systemic diseases, such as: thyroid disease (hypothyroidism and hyperthyroidism), adrenal glands, liver, kidney and blood disorders (von Willebrand disease, idiopathic thrombocytopenic purpura, and leukemia) based on the patient's statement and medical records. Daily and regular intake of vitamin D supplements for the past three months. Taking medications that affect the menstrual cycle and bleeding, such as: oral hormonal contraceptives, anticoagulants, serotonin inhibitors, antipsychotics, corticosteroids, hormonal supplements, phenytoin, or herbal supplements such as soy and ginseng. Having premenstrual syndrome. Have any absolute or relative contraindications to the use of combined contraceptive pills, including breast cancer, endometrial cancer, liver disease, deep vein thrombosis, smoking in people 35 years and older, cardiovascular disease, history of stroke, Diabetes, hypertension, migraine, hyperlipidemia, conditions requiring complete immobility, inflammatory bowel disease, major depression, and epilepsy require medication.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into two groups: COCs group, COCs group - Vitamin D using random blocking method with the size of four and six blocks with 1: 1 allocation ratio. Assignment sequence with the help of the researcher and using the software Random Allocation Software will be specified. To conceal the allocation, closed opaque envelopes will be prepared and numbered according to the number of samples. Envelope preparation and random allocation sequencing will be performed by the non-research person.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The drugs and their placebo will be prepared by the pharmaceutical company in a completely similar way in terms of shape, color and smell. The researcher, participants, data analyst, and outcome reviewer are unaware of the type of intervention received.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Research department., third floor., central construction number 2., Tabriz University of Medical Sciences., Golgasht Street., Azadi Avenue
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Tabriz
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Postal code
5138947977
Approval date
2021-02-14, 1399/11/26
Ethics committee reference number

IR.TBZMED.REC.1399.1041

Health conditions studied

1

Description of health condition studied
Ovulatory dysfunction bleeding
ICD-10 code
N93.8
ICD-10 code description
Other specified abnormal uterine and vaginal bleeding

Primary outcomes

1

Description
Menstrual bleeding rate
Timepoint
Before the intervention, one month, two months and three months after the start of the intervention, after the end of the intervention
Method of measurement
Higham Questionnaire

2

Description
Number of menstrual bleeding days
Timepoint
Before the intervention, one month, two months and three months after the start of the intervention, after the end of the intervention
Method of measurement
Calendar

Secondary outcomes

1

Description
The duration of the menstrual cycle
Timepoint
Before the intervention, one month, two months and three months after the start of the intervention, after the end of the intervention
Method of measurement
Calendar

2

Description
Quality of life score
Timepoint
Before the intervention, after the end of the intervention
Method of measurement
SF-36 questionnaire

3

Description
side effects
Timepoint
The first, second and third months after the start of the intervention
Method of measurement
Side effects questionnaire

4

Description
Satisfaction of treatment
Timepoint
after the end of the intervention
Method of measurement
Patient Satisfaction Questionnaire

Intervention groups

1

Description
Control group: LD capsules (containing 30 micrograms of ethinyl estradiol and 150 micrograms of levonorgestrel), 21 tablets with 9 placebo capsules daily, one for three cycles
Category
Treatment - Drugs

2

Description
Intervention group: Combination capsules containing vitamin D (1000 units of cholecalciferol) and LD (30 micrograms of ethinyl estradiol and 150 micrograms of levonorgestrel) of 21 and then 9 vitamin D capsules daily, one for three cycles
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available