Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of supplementation on the combined pill continuation rate and Harassment rate of its side effects: a randomized controlled trial

Protocol summary

Summary

The aim of this trial is to determine the effect of supplementation during the 7 day with no pill on continuation rate and harassment rate of side effects in new combined pill users. Women who want to start using combined oral contraceptive pills as contraception will be assessed for eligibility criteria. 330 eligible women who give written informed consent will complete a self-administered questionnaire including socio-demographic and reproductive characteristics questions. Then, the subjects will randomly be allocated into three groups using permuted block randomization with block sizes of 3 and 6 (determined by a computerized random number). For 6 cycles, every 28 days subjects in the first group will take 21 LD pills (each pill contains 30 µg ethinyl estradiol and 150 µg levenorgesterol) and 7 multivitamins pills, the second group 21 LD and 7 Placebo pills and the third group 21 LD pills and no pill in the following 7 days. Sequentially numbered opaque sealed envelopes will be used for the allocation concealment which will be opened sequentially after completing the baseline questionnaire by each recruited person. For six months or until discontinuation of the pills, all three group subjects will fill in a questionnaire including some questions about using the pills, harassment rate of side effects and satisfaction from the pills during the cycle when they come to get the next blister of pills in every cycle visit. ANOVA and Cox regression will be used for the data analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210093706N15**
Registration date: **2012-12-09, 1391/09/19**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2012-12-09, 1391/09/19

Registrant information

Name
Sakineh Mohammad-Alizadeh-Charandabi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3477 2699
Email address
alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-06-05, 1392/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplementation on the combined pill continuation rate and Harassment rate of its side effects: a randomized controlled trial

Public title

The effect of supplementation on the combined pill continuation rate and Harassment rate of its side effects

Purpose

Health service research

Inclusion/Exclusion criteria
Inclusion criteria: married no pregnant women aged 18-40 years; intention to start using Low dose (LD) combined pills as a contraceptive method; being literate; not taking combined hormonal methods at least in the past three months. Exclusion criteria: plan to get pregnant in 6 months; not having medical eligibility criteria for contraceptive use.
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **330**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
The investigators, participants, and evaluators will be blinded to assignment into the two groups (the groups taking the pills + multivitamins or taking the pills + placebo) but blinding to the third group taking only the pills (7 day with no pill) is not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences, Reaserch deputy
Street address
Golgasht
City
Tabriz
Postal code
Approval date
2012-12-03, 1391/09/13
Ethics committee reference number
91146

Health conditions studied

1

Description of health condition studied
continuation rate of oral contraceptives
ICD-10 code
Y42.4
ICD-10 code description
oral contraceptives

Primary outcomes

1

Description
Continuation rate
Timepoint
monthly
Method of measurement
interview

2

Description
Harrasement rate of side effects of the pills
Timepoint
daily
Method of measurement
interview

Secondary outcomes

1

Description
Correct use of the pills
Timepoint
monthly
Method of measurement
interview

Intervention groups

1

Description
taking 7 multivitamins pills monthly during the 7 day no pill period for 6 months (each pill contains Vitamin A 5000 I.U. , Vitamin B1 1.5 mg , Vitamin B2 1.7 mg , Vitamin B6 2 mg , VitaminC 60 mg , VitaminD3 400 I.U. , Vitamin E 15 I.U. , Vitamin B12 6 mg , Nicotinamid 20 mg and Folic Acid 400 mg)
Category
Prevention

2

Description
taking 7 placebo pills monthly during the 7 day no pill period for 6 months
Category
Prevention

3

Description
No intervention (no pill taking on the 7 days interval between taking every cycle pills)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sahid-Madani Health Center
Full name of responsible person
Laya Foroghy
Street address
Shamse Tabrizi Street
City
Marand

2

Recruitment center
Name of recruitment center
Alzahra Health Center
Full name of responsible person
Laya Foroghy
Street address
Ohani Street
City
Marand

3

Recruitment center
Name of recruitment center
Mahbobeh-Sadeghi Health Center
Full name of responsible person
Laya Foroghy
Street address
Abyari square
City
Marand

4

Recruitment center
Name of recruitment center
Shadid-Motahary Health Center
Full name of responsible person
Laya Foroghy
Street address
Jolfa Street
City
Marand

5

Recruitment center
Name of recruitment center
Shahid-Kalantary Health Post
Full name of responsible person
Laya Foroghy
Street address
Yaldor Street
City
Marand

6

Recruitment center
Name of recruitment center
Shahid- kasaei Health post
Full name of responsible person
Laya Foroghy
Street address
Shahid kasaei Street
City
Marand

7

Recruitment center
Name of recruitment center
Shahid-Afrazmand Health Post
Full name of responsible person
Laya Foroghy
Street address
Yaldor Street
City
Marand

8

Recruitment center
Name of recruitment center
Shahid- Beheshti Health Post
Full name of responsible person
Laya Foroghy
Street address
Emam Khomeini Street
City
Marand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Kazem Shakouri
Street address
Golgasht
City
Tabriz
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
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
Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences
Full name of responsible person
Laiya Forougi
Position
MSc student in midwifery
Other areas of specialty/work
Street address
South Shariatie
City
Tabriz
Postal code
Phone
+98 41 1479 7713
Fax
Email
alizades@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of nursing and midwifery, Tabriz university of medical sciences
Full name of responsible person
Sakineh Mohammad-Alizadeh-Charandabi
Position
PhD in reproductive health
Other areas of specialty/work
Street address
South Shariatie
City
Tabriz
Postal code
Phone
+98 41 1479 7713
Fax
Email
alizades@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Faculty of Nursing & Mi8dwifery, Tabriz University of Medical Sciences
Full name of responsible person
Sakineh Mohammad-Alizadeh-Charandabi
Position
PhD in reproductive health
Other areas of specialty/work
Street address
Shariatie Ave.
City
Tabriz
Postal code
Phone
+98 41 1479 7713
Fax
Email
alizades@tbzmed.ac.ir
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