

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 levonorgestrol) 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**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 & 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**

Shariatie Ave.

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

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*