Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Randomized, Controlled Trial of Levonorgestrel Vs. The Yuzpe Regimen as Emergency Contraception Method among Iranian Women

Protocol summary

Summary

We aimed to compare acceptability of levonorgestrel with the Yuzpe regimen among Iranian women based on their side-effects and resulting changes in the amount and pattern of menses. five hundred twenty nine participants aged 15-49 having regular menses and one act of unprotected intercourse within 72 h were included in the double-blind, controlled trial and randomly assigned into LNG (n=263) and HD (n=266) groups, receiving levonorgestrel 0.75 mg given 12 h apart and ethinyl estradiol 100 µg plus 0.5 mg levonorgestrel 0.5 mg repeated after 12 h, respectively. Between 12 Sep 2006 and 25 Jun 2007 After complying with inclusion criteria participants were asked to sign the written consent. Participants were then classified into two groups (i.e. HD regimen and LNG regimen groups) according to balanced black randomization. Four tablets in the same size, shape, and color were put in each set. Neither the obstetrics, nor the participants were aware of the type of tablets in each set (double-blind). Only the person responsible for randomization was aware of the contents of the sets according to the serial numbers stuck on the sets. Levonorgestrel regimen (LNG group) consisted of two sets; each one contained a 0.75 mg levonorgestrel and a placebo tablet; the pills in each set were taken at once and the sets were taken 12 h apart. Yuzpe regimen (HD group) consisted of four white tablets; two HD pills were put in a set. The pills in each set were taken at once and the sets were taken 12 h apart. The third dose (two pills) was also given to the participants to be taken if regurgitating within two hours of drug administration. The first set of tablets was taken in presence of the obstetrics and the second set was taken at home 12 h later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091112307N2**
Registration date: **2013-09-14, 1392/06/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-09-14, 1392/06/23

Registrant information

Name

Fatemeh Sadat Hoseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8890 7062

Email address

fshoseini@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

partly by Deputy Ministry for Research Tehran University of Medical Sciences, grant #132/10442 and in part by Population Family and School Health Dept., Ministry of Health and Medical Education

Expected recruitment start date

2006-08-12, 1385/05/21

Expected recruitment end date

2007-05-25, 1386/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized, Controlled Trial of Levonorgestrel Vs. The Yuzpe Regimen as Emergency Contraception Method among Iranian Women

Public title
A Randomized, Controlled Trial of Levonorgestrel Vs. The Yuzpe Regimen as Emergency Contraception Method among Iranian Women
Purpose
Prevention
Inclusion/Exclusion criteria
Eligible participants were sexually active women aged between 15 and 49 years having regular menstrual cycles of 24-42 days. We also included women having only one act of unprotected intercourse within current cycle and they were asked to take the pills within 72 h of the unprotected intercourse. In addition, the failed contraceptive method was determined to be condom or conventional method. Breast-feeding women were also included provided that their baby was older than 6 months. Exclusion criteria were breast-feeding women with their baby younger than 6 months, hormonal contraindications in their current cycle, use of hormonal contraceptives, uncertainty about the time of LMP, and suspected pregnancy
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: **529**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Deputy of Research of Tehran University of Medical Science
Street address
Floor 6th,Deputy of Research of Tehran University of Medical Science,Ghods street,Keshavarz Blvd.
City
Tehran
Postal code
1417653761
Approval date
2006-07-12, 1385/04/21
Ethics committee reference number
130/677

Health conditions studied

1

Description of health condition studied
Family planning / Contraception
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The Comparison of side effects of Levonorgestrel Vs. The Yuzpe Regimen as Emergency Contraception Method among Iranian Women
Timepoint
after a week, one week after the latest Expected mense
Method of measurement
Questionnaire, talk to women

2

Description
The Comparison of pattern of menses of Levonorgestrel Vs. The Yuzpe Regimen as Emergency Contraception Method among Iranian Women
Timepoint
at the first day, after a week, one week after the latest Expected mense
Method of measurement
Questionnaire, talk to women

3

Description
The Comparison of unwanted pregnancy rate of Levonorgestrel Vs. The Yuzpe Regimen as Emergency Contraception Method among Iranian Women
Timepoint
one week after the time of latest Expected mense
Method of measurement
Questionnaire,taik to women,Serum BHCG titer in retarded mense

Secondary outcomes

1

Description
Determination of the knowledge of iranian women about emergency contraception methods

Timepoint
at the first day
Method of measurement
Questionnaire,talk to women

Intervention groups

1

Description
Levonorgestrel regimen (LNG group) consisted of two sets; each one contained a 0.75 mg levonorgestrel and a placebo tablet; the pills in each set were taken at once and the sets were taken 12 h apart
Category
Prevention

2

Description
Yuzpe regimen (HD group) consisted of four white tablets; two HD pills were put in a set. The pills in each set were taken at once and the sets were taken 12 h apart
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Family planning of health care centers of Gilan University of Medical Sceinces
Full name of responsible person
Street address
City
Rasht/Bandar Anzali

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
by Deputy Ministry for Research Tehran University of Medical Sciences,Population Family and School H
Full name of responsible person
Mommad Eslami,Akbar Fotohi
Street address
Floor 6th, Deputy of Research of Tehran University of Medical Science, Ghods street, Keshavarz Blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
by Deputy Ministry for Research Tehran University of Medical Sciences,Population Family and School H
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
Teran University of Medical Sciences
Full name of responsible person
Fatemeh Sadat Hoseini
Position
Research Employee and Student PhD of Reproductive Biology
Other areas of specialty/work
Street address
Floor 6th,Deputy of Research of Tehran University of Medical Science,Ghods street,Keshavarz Blvd.
City
Tehran
Postal code
1417653761
Phone
+98 21 8163 3619
Fax
Email
fshoseini@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Sadat Hoseini
Position
Research Employee and Student PhD of Reproductive Biology
Other areas of specialty/work
Street address
Floor 6th,Deputy of Research of Tehran University of Medical Science,Ghods street,Keshavarz Blvd.
City
Tehran
Postal code
Phone
+98 21 8168 3619
Fax
Email
fshoseini@razi.tums.ac.irhoseini_fs@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Sadat Hoseini

Position
Research Employee and Student PhD of Reproductive Biology

Other areas of specialty/work

Street address
Floor 6th,Deputy of Research of Tehran University of Medical Science,Ghods street,Keshavarz Blvd.

City
Tehran

Postal code
1417653761

Phone
+98 21 8163 3619

Fax

Email
fshoseini@razi.tums.ac.ir hoseini_fs@yahoo.com

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