

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 block 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, talk 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 Sciences

**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*