

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The comparison between efficacy of single dose levonorgestrel, with two dose levonorgestrl and Yuzpe as an emergency contraception

Protocol summary

Summary

The aim of this clinical trial multi central study was the comparison between efficacy of levonorgestrel single dose, with two doses of levonorgestrl and Yuzpe method as an emergency contraception. Informed consent was obtained. Inclusion Criteria: women within 120 hours of unprotected intercourse; regular menstrual cycles; No current use of any hormonal contraception; non smoker Exclusion Criteria: One or more acts of unprotected intercourse more than 120 hours current or recent use of hormonal methods of contraception; Women were randomly allocated in three groups: Group A received two doses of 0.75 mg LNG taken 12 h apart, Group B received the single dose of LNG(1.5 mg); and Group C received the yuzpe regime(four tab ocp contain 30 microgram ethinyl estradiol plus 0.15 mg levonorgestrel, each given twice, 12 hours apart totally 8 tab). The main variable is success rate in three interventional methods; B hCG test was performed after 3 weeks menstruation delay .Intrauterine pregnancy was confirmed by abdominal ultrasound .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106186826N1**

Registration date: **2011-07-24, 1390/05/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-24, 1390/05/02

Registrant information

Name

Mahshid Bokaie

Name of organization / entity

Shahid Sadougi university of medical sciences,Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1751

Email address

mah_bokaie@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadougi University of Medical Sciences

Expected recruitment start date

2009-05-22, 1388/03/01

Expected recruitment end date

2011-05-07, 1390/02/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between efficacy of single dose levonorgestrel, with two dose levonorgestrl and Yuzpe as an emergency contraception

Public title

Three method for emergency contraception

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion Criteria: present within 120 hours of unprotected intercourse; regular menstrual cycles and no current use of hormonal contraception Exclusion Criteria: One or more acts of unprotected intercourse more than 120 hours

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadougi University of Medical Sciences

Street address

Yazd

City

Yazd

Postal code

Approval date

2009-02-11, 1387/11/23

Ethics committee reference number

107515

Health conditions studied

1

Description of health condition studied

Family planning

ICD-10 code

Z30

ICD-10 code description

Contraceptive management

Primary outcomes

1

Description

Unwanted pregnancy

Timepoint

Three week after unprotected intercourse

Method of measurement

Beta HCG titer

Secondary outcomes

1

Description

Menstrual pattern in next month

Timepoint

Next month

Method of measurement

Using check list

Intervention groups

1

Description

Longel (levonorgestrel 0.75 mg: Iran hormon

Company:two tab(1.5 mg) single dose

Category

Treatment - Drugs

2

Description

Longel (levonorgestrel 0.75 mg) Iran hormon

Company:one tab (0.75 mg) given twice, 12 hours apart

Category

Treatment - Drugs

3

Description

OCP Ovacept (LD:30microgr ethinylestradiol +15mg

levonorgestrel:Aburahan Company :four tab each given twice, 12 hours apart)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Azad Shahr health center

Full name of responsible person

Street address

City

Yazd

2

Recruitment center

Name of recruitment center

Akbari health center

Full name of responsible person

Street address

City

Yazd

3

Recruitment center

Name of recruitment center

Rahmat Abad health center

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadougi University of Medical Sciences

Full name of responsible person

Fatemeh Ezodini Ardekani

Street address

Bahonar sq- Yazd -Iran

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Sadougi 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

Shahid Sadougi University of Medical Sciences

Full name of responsible person

Mahshid Bokaie

Position

MS

Other areas of specialty/work

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Mahshid Bokaie

Position

MS

Other areas of specialty/work

Street address

Nursing & Midwifery Collage

City

Yazd

Postal code

Phone

Fax

Email

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