

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Efficacy of oral versus vaginal progestogens in the maintenance of early pregnancy in women with recurrent miscarriages

Protocol summary

Study aim

To compare the effectiveness of oral versus vaginal progestogens in treating recurrent miscarriages.

Design

108 participants, parallel-group, no blindness, randomized control trial, phase 4

Settings and conduct

study was performed at Post Graduate Medical Institute (PGMI), Lady Reading Hospital Peshawar,

Participants/Inclusion and exclusion criteria

Inclusion criteria: pregnant women; aged 16-40 years, with a history of at least three recurrent miscarriages; visiting at or less than 7 weeks of gestation. Exclusion criteria: patients with threatened miscarriage, structural uterine abnormality distorting the cavity, the absence of fetus cardiac activity (missed abortion), contraindications to progestogens use (e.g. allergy to progesterone, patient with breast carcinoma)' inadequate treatment compliance.

Intervention groups

Oral progestogen was given to group A in the dose of 10mg twice a day for 12 weeks in the morning and evening after meals, while group B received vaginal progestogens in the dose of 200mg twice a day for 12 weeks.

Main outcome variables

Miscarriage

General information

Reason for update

Acronym

Progestogens for recurrent miscarriages trial

IRCT registration information

IRCT registration number: **IRCT20230117057148N1**

Registration date: **2023-04-06, 1402/01/17**

Registration timing: **retrospective**

Last update: **2023-04-06, 1402/01/17**

Update count: **0**

Registration date

2023-04-06, 1402/01/17

Registrant information

Name

Rizwan Faisal

Name of organization / entity

Rehman Medical Institute

Country

Pakistan

Phone

+92 333 9120587

Email address

drizwanfaisal@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-02, 1399/01/14

Expected recruitment end date

2020-09-15, 1399/06/25

Actual recruitment start date

2020-04-02, 1399/01/14

Actual recruitment end date

2020-09-15, 1399/06/25

Trial completion date

2020-09-15, 1399/06/25

Scientific title

Efficacy of oral versus vaginal progestogens in the maintenance of early pregnancy in women with recurrent miscarriages

Public title

Oral versus vaginal progestogens in women with recurrent miscarriages

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy Aged 16-40 years, A history of at least three recurrent miscarriages At or less than 7 weeks of gestational age

Exclusion criteria:

Threatened miscarriage, Breast carcinoma Structural uterine abnormality distorting the cavity, Absence of fetal cardiac activity (missed abortion), Contraindications to progesteron use (e.g. allergy to progesterone) Inadequate treatment compliance

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **108**

Actual sample size reached: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

All the included patients were given code from 1-108, these codes were entered in the computer , through SPSS random numbers were generated. Computer itself divided numbers randomly in to 2 groups i.e 54 in one and 54 in other group.

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

Ethics Committee of the college of physicians and surgeons Pakistan

Street address

House No. T-825, Street No. 5, Opposite

City

Peshawar

Postal code

25000

Approval date

2020-03-01, 1398/12/11

Ethics committee reference number

CPSP/REU/OBG-2014-022-6174

Health conditions studied

1

Description of health condition studied

recurrent miscarriages

ICD-10 code

O03

ICD-10 code description

Spontaneous abortion

Primary outcomes

1

Description

Pregnancy

Timepoint

12 weeks of gestation

Method of measurement

ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Interventional Group 1: This group will be given oral progestogens in a dose of 10mg twice a day in morning and evening after meals for 12 weeks. Efficacy will be measured by continuation of pregnancy beyond 12 weeks. All the data will be recorded in predesigned data. Transvaginal ultrasound will be performed at 7, 9 and 12 week of gestation. Ultrasonography will be looked for presence of fetal cardiac activity. This group will also serve as control as it is the standard routine route by which progestogens are given.

Category

Treatment - Other

2

Description

Intervention group 2: This group was prescribed vaginal progestogens in a dose of 200mg twice a day for 12 weeks. Efficacy was measured by continuation of pregnancy beyond 12 weeks. All the data will be recorded in predesigned data. Transvaginal ultrasound will be performed at 7, 9 and 12 week of gestation. Ultrasonography will be looked for presence of fetal cardiac activity

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Lady Reading Hospital Peshawar

Full name of responsible person

Dr.Laiyla Shinwari

Street address

Near Andersshaher, Peshawar City

City

Peshawar

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Phone

+92 91 9211430

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drrizwanfaisal@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lady Reading Hospital

Full name of responsible person

Dr Rehana

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Lady Reading Hospital

Proportion provided by this source

10

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Lady Reading hospital

Full name of responsible person

Dr Laiyla Shinwari

Position

FCPS Trainee

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Consultant

Latest degree

Specialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Patient data related with type, gravidity, parity etc will be shared

When the data will become available and for how long

After publication of the manuscript till 1 year

To whom data/document is available

Whoever designs relevant research will be given data

Under which criteria data/document could be used

When one ensures that secrecy will be maintained will be given data

From where data/document is obtainable

one will get it by emailing me on
rizwan.faisal@rmi.edu.pk

What processes are involved for a request to access data/document

Simply by email one can request for data

Comments

Nil