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
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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 progestron 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 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 Andershaher, Peshawar City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Lady Reading Hospital
Full name of responsible person
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Street address
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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 updating data

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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