

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of pregnancy outcome following oral and intramuscular progesterone use in preterm labor

Protocol summary

Study aim

Comparison of oral and intramuscular progesterone in preterm labor

Design

In this clinical trial with phase 2-3, with two intervention groups and without any control group, 146 patients divides randomly into two groups of 73. The study will be done as single blind study.

Settings and conduct

Weekly, all the patients of two groups are followed up in the gynecology clinic of Afzalipour hospital. After delivery, delivery condition and time, delivery method, newborn weight, APGAR score and the need for NICU hospitalization are investigated. The complications followed by each of oral and injectable medications are registered. Regarding the study being single blinded, patients, physicians and midwives are aware of the treatment type and just the data analyzer is blind to the medication type.

Participants/Inclusion and exclusion criteria

Inclusion: preterm labor, single pregnancy, live fetus, healthy amniotic sac, gestation age (24-36 weeks), lack of cerclage, labor pains, cervical dilatation ≥ 1 cm.

Exclusion: PPRM, vaginal bleeding, cervical dilation > 3 cm, fetal death or distress, maternal systemic diseases, known uterine anomalies, history of taking any medication other than the usual supplements, polyhydramnios and oligohydramnios, fetal anomaly, suspicion of intrauterine infection, being dangerous for the mother to continue the pregnancy, lack of cooperation of mothers.

Intervention groups

In the intervention group one, patient received a 200 mg capsule of luteogel daily containing micronized progesterone by Tesnim company, and in the second intervention group, patients received a weekly prolestone 250 mg ampoule product of Bayer company treatment continued until delivery or 36 weeks. Patients are visited weekly.

Main outcome variables

Birth weight, gestational age at delivery, frequency of preterm labor in each group, duration of latency and frequency of admitted infants in each group

General information

Reason for update

In the sample size section, the number of samples in each group was written, which was corrected and the total sample size was 146 people. This study was randomized and modified in the relevant section.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190623043981N1**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **retrospective**

Last update: **2021-12-21, 1400/09/30**

Update count: **3**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Moeeneh Barkhori mehni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3252 1679

Email address

moeeneh1367@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-23, 1397/12/04

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pregnancy outcome following oral and intramuscular progesterone use in preterm labor

Public title

Comparison of oral and intramuscular progesterone in preterm labor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Single-tone pregnancy alive fetus intact membrane gestational age between 24-36 weeks preterm labor lack of cerclage labor pains in the form of contractions alternating 2 times in 10 minutes or 8 times in 60 minutes cervical dilatation equal to or greater than 1 cm ultrasound of the first 3 months of pregnancy

Exclusion criteria:

vaginal bleeding known uterine anomalies fetal anomalies suspicion of intrauterine infection preterm premature rupture of membranes (PPROM) cervical dilation greater than 3 cm fetal death or fetal distress maternal systemic diseases history of taking any medication other than the usual supplements during pregnancy polyhydramnios and oligohydramnios being dangerous for the mother to continue the pregnancy due to medical reasons lack of cooperation of mothers during study

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 146

Randomization (investigator's opinion)

Randomized

Randomization description

After stopping labor pain successfully, 146 patients in the form of randomization allocation are divided into to two groups (A= 73 and B= 73) according to random number table. This study was performed as a single-blind study. The patient and physician were aware of the type of treatment and only the person evaluating the data was unaware of the type of treatment at the end. The statistical consultant performed randomization and provided the results to the researcher and the researcher assigned the participants to the interventions groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

during this study, the data evaluator was unaware of the treatment types, while physician and patient blinding was impossible as the difference of the used methods was obvious to the them.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2019-02-22, 1397/12/03

Ethics committee reference number

IR.KMU.AH.REC.1397.155

Health conditions studied**1****Description of health condition studied**

Preterm labour

ICD-10 code

O60.0

ICD-10 code description

Preterm labour without delivery

Primary outcomes**1****Description**

Birth weight

Timepoint

after delivery

Method of measurement

Scale

2

Description

gestational age at delivery

Timepoint

after delivery

Method of measurement

patient documents

3

Description

latency period

Timepoint

from beginning of intervention until delivery

Method of measurement

patient documents

4

Description

number of hospitalized neonates in each group

Timepoint

after delivery

Method of measurement

patient documents

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group one, until 36 weeks of pregnancy, 200 mg capsule containing micronized progesterone called luteogel produced by Tasnim company will be given daily .

Category

Treatment - Drugs

2

Description

Intervention group two a 250 mg progesterone ampoule containing hydroxy caproate produced of Byer company will be given weekly and treatment will continue until 36 weeks of pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipor hospital

Full name of responsible person

Moeeneh Barkhori Mehni

Street address

Imam Khomeini Highway (RA), next to Shahid Bahonar University, Afzalipour Medical Education Center

City

kerman

Province

Kerman

Postal code

۷۶۱۶۹۱۳۹۱۱

Phone

+98 34 3132 8000

Email

moeeneh1367@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3855

Email

Abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

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

Kerman University of Medical Sciences

Full name of responsible person

Moeeneh Barkhori Mehni

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Unit 8 Shyda Building Khajo 34 Street

City
Kerman

Province
Kerman

Postal code
7617778555

Phone
+98 34 3252 1679

Email
moeeneh1367@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Moeeneh Barkhori Mehni

Position
Resident Gyn And Obs

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Afzalipour Hospital Emam Highway

City
Kerman

Province
Kerman

Postal code
7616914115

Phone
+98 34 3132 8307

Email
moeeneh1367@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Moeeneh Barkhori

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
unit 8 Shyda building Khajo 34 street

City
Kerman

Province
Kerman

Postal code
7617778555

Phone
+98 34 3252 1679

Email
moeeneh136@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total data

When the data will become available and for how long

Starting six months after the publication of the article

To whom data/document is available

Researchers, students and doctors

Under which criteria data/document could be used

To perform clinical examination

From where data/document is obtainable

General or scientific responsible person

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

Submit the proposal to the responsible person

Comments