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: PPROM, 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 proletone 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)

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+98 34 3252 1679

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

1

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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
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
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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