Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

A clinical trial to comparison the effectiveness of 17 α-Hydroxyprogesterone caproate with routine prenatal care on prevention of preterm labor in patients with a history of preterm labor.

Protocol summary

Study aim
The effectiveness of 17 α-Hydroxyprogesterone caproate with routine prenatal care on prevention of preterm labor in patients with a history of preterm labor.

Design
In this pragmatic double-blind, controlled clinical trial, 100 pregnant women with history of preterm labor were assigned into parallel groups using the table of random numbers in a community-based setting.

Settings and conduct
Pregnant women with history of preterm labor at the Imam Khomeini Hospital, Sari, Iran, were chosen. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age higher than 18 years; history of preterm labor. Exclusion criteria: Active labor phase; premature rupture of the fetal membranes; preeclampsia; vaginal bleeding; dilation greater than 3cm and cervical length less than 25mm; intra-amniotic infection; using tocolytic drugs; allergic to progesterone.

Intervention groups
The control group will receive routine prenatal care without any special interventions. The intervention group will receive 250 mg intra-muscular 17 α-Hydroxyprogesterone caproate at 16 weeks of gestation up to 37 weeks of gestation every week.

Main outcome variables
Evaluation and comparison of the mean gestational age at birth, prevalence of preterm labor, and the mean neonatal birth weight in the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190309042978N2**
Registration date: **2019-03-19, 1397/12/28**
Registration timing: **prospective**

Last update: **2019-03-19, 1397/12/28**
Update count: **0**

Registration date
2019-03-19, 1397/12/28

Registrant information
Name
Hamed Jafarpour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3336 1700
Email address
h.jafarpour1@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to comparison the effectiveness of 17 α-

Hydroxyprogesterone caproate with routine prenatal care on prevention of preterm labor in patients with a history of preterm labor.

Public title
Effect of 17 α-Hydroxyprogesterone caproate on prevention of preterm labor.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age higher than 18 years History of preterm labor
Exclusion criteria:
Active labor phase Premature rupture of the fetal membranes Preeclampsia Vaginal bleeding Dilation greater than 3cm and cervical length less than 25mm Intra-amniotic infection Using tocolytic drugs Allergic to progesterone
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Totally 100 pregnant women with history of preterm labor at the Imam Khomeini Hospital, Sari, Iran, were chosen. The participants were allocated into groups of intervention and control using the table of random numbers based on computer programs.
Blinding (investigator's opinion)
Double blinded
Blinding description
Pregnant women with history of preterm labor at the Imam Khomeini Hospital, Sari, Iran, were chosen. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Vice Chancellor for Research, Mazandaran University of Medical Sciences, Farah Abad Road
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2016-10-18, 1395/07/27
Ethics committee reference number
Ir.mazums.imam hospital.rec.96.2741

Health conditions studied

1

Description of health condition studied
Preterm labor
ICD-10 code
O60
ICD-10 code description
Preterm labour and delivery

Primary outcomes

1

Description
The mean gestational age at birth
Timepoint
After intervention
Method of measurement
Based on the first day of the last menstruation period or ultrasound

2

Description
Prevalence of preterm labor
Timepoint
After intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
The mean neonatal birth weigh
Timepoint
After intervention
Method of measurement
Scale

Intervention groups

1

Description
Intervention group: The intervention group will receive 250 mg intra-muscular 17 α-Hydroxyprogesterone caproate at 16 weeks of gestation up to 37 weeks of gestation every week.
Category
Prevention

2

Description
Control group: The control group will receive routine prenatal care without any special interventions.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Hamed Jafarpour
Street address
Imam Khomeini Hospital, Amir Mazandarani Street
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 1700
Email
h.jafarpour@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Saeidi
Street address
Vice Chancellor for Research, Mazandaran University of Medical Sciences, Farah Abad Road
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3335 2725
Email
Admission@mazums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Hamed Jafarpour
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Others
Street address
Imam Khomeini Hospital, Amir Mazandarani Street
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 1700
Email
h.jafarpour@mazums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Hamed Jafarpour
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
Others
Street address

Imam Khomeini Hospital, Amir Mazandarani Street

City
Sari

Province
Mazandaran

Postal code
4816633131

Phone
+98 11 3336 1700

Email
h.jafarpour@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Hamed Jafarpour

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
Others

Street address
Imam Khomeini Hospital, Amir Mazandarani Street

City
Sari

Province
Mazandaran

Postal code
4816633131

Phone
+98 11 3336 1700

Email
h.jafarpour@mazums.ac.ir

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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Information on the main outcome or the like can be shared.

When the data will become available and for how long
6 months after printing results

To whom data/document is available
Our data will only be available to researchers working at science centers and universities

Under which criteria data/document could be used
Our data will be available for scholars working at science centers and universities

From where data/document is obtainable
Hamed Jafarpour provides the data analysis to the applicants via email: h.jafarpour@mazums.ac.ir

What processes are involved for a request to access data/document
Applicants can respond to the email of the respondent and receive a response within a week.

Comments