

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Estimating the therapeutic effect of 17 alpha-hydroxy progesterone caproate in preventing preterm labor after inhibiting uterine contractions

Protocol summary

Registration timing: **retrospective**

Summary

Objectives: This research aims to investigate the effect of 17 alpha-hydroxyprogesterone caproate on the prevention of preterm labor after inhibiting uterine contractions in Shariati hospital of Bandar Abbas. **Design:** The research population consists of all women with single pregnancy who visited Shariati hospital due to premature uterine contractions within 26-34 weeks of pregnancy. 100 subjects belonged to the treatment group and 100 others were in the control. This research is of a randomized clinical trial type. It is also a single-blind prospective and mono-centered study conducted in a simple randomized method. **Setting and conduct:** there are two groups involved, a control group and a treatment which tests the effect of 17 alpha-hydroxyprogesterone caproate. **Interventions:** patients were given 2 doses of 12 mg of betamethasone within 24 hours (with an interval of 12 hours) for fetal lung maturation. Within 48hours of the stopping of uterine contractions, the patients were randomly assigned to either the treatment or the control group. The former received an intramuscular injection of 17 alpha-hydroxyprogesterone (500 mg) once a week. The latter group received no such injection. **Inclusion criteria:** pregnancy age between 26-34 weeks, presence of premature uterine contractions. **Exclusion criteria:** pregnancy age ≥ 34 weeks, premature rupture of membranes, Chorioretinitis, pre-labor blood loss as in placental abruption. **main outcome measures:** Primary variable: determining the prevention of preterm labor after inhibiting uterine contractions under the effect of 17 alpha-hydroxyprogesterone. Secondary variable: none

Last update:

Update count: **0**

Registration date

2016-01-31, 1394/11/11

Registrant information

Name

Razieh Rrajabzadeh

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 7104

Email address

barvari@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Hormozgan University of Medical Sciences

Expected recruitment start date

2014-07-30, 1393/05/08

Expected recruitment end date

2014-12-04, 1393/09/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Estimating the therapeutic effect of 17 alpha-hydroxy progesterone caproate in preventing preterm labor after inhibiting uterine contractions

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050119396N3**

Registration date: **2016-01-31, 1394/11/11**

Public title

Estimating the therapeutic effect of 17 alpha-hydroxy progesterone caproate in preventing preterm labor after inhibiting uterine contractions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Between 26-34 weeks pregnancy age; There premature uterine contractions. Exclusion criteria: the pregnancy age above 34 weeks (since in this group there would be no reason for preventing uterine contractions due to the fetal lung maturation); preterm rupture of membranes; corioamnionite, blood loss prior to the labor due to placental abruption or previa; multiple pregnancies; concomitant systemic diseases (preeclampsia, gestational diabetes (GDM); cardiovascular diseases; kidney diseases; asthma; hyperthyroid; ...).

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

This study will be randomly sampling.

Secondary Ids

empty

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

Ethics committee of Hormozgan University of Medical Sciences

Street address

vice chancellor for research and technology, Shahid Mohamadi Hospital

City

Bandar Abbas

Postal code**Approval date**

2013-07-22, 1392/04/31

Ethics committee reference number

92-4-31-2

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

Preterm labour

ICD-10 code

O60.1

ICD-10 code description

Preterm labour without delivery

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

The prevention of preterm birth after inhibition of uterine contractions.

Timepoint

48 hours after the intervention.

Method of measurement

Check up and examination

Secondary outcomes

empty

Intervention groups**1****Description**

The treatment group received a weekly intramuscular injection of 17 alpha-hydroxyl progesterone (500 mg). They were advised to continue it until their 36th week of pregnancy at home. Within 48 hours of hospitalization (prior to their discharge) the patient was once again examined by the researcher. This drug made by pharmaceutical company bayer of schering pharma.

Category

Treatment - Drugs

2**Description**

The control group would receive no such injection. Within 48 hours of hospitalization (prior to their discharge) the patient was once again examined by the researcher.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hospital Dr. Ali Shariati

Full name of responsible person

azin alavi

Street address

Hospital Dr. Ali Shariati

City

St. martyr Naser-bandar abbas

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hormozgan University of Medical Sciences

Full name of responsible person

Azim Nejatizadeh

Street address

Vice Chancellor for research of Hormozgan University of Medical Sciences

City

Bandar Abbas

Grant name**Grant code / Reference number**

-

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

Yes

Title of funding source

Hormozgan University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shariati Hospital

Full name of responsible person

Azin Alavi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shariati Hospital, St. shahid Nasr- Bandar Abbas

City

Bandar Abbas

Postal code**Phone**

+98 76 3333 2424

Fax**Email**

azin_alavi@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shariati hospital, Hormozgan University of Medical Sciences

Full name of responsible person

Azin Alavi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shariati hospital, Hormozgan University of Medical Sciences

City

Bandar Abbas

Postal code**Phone**

+98 76 3333 2424

Fax**Email**

azin_alavi@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shariati hospital, Hormozgan University of Medical Sciences

Full name of responsible person

Razieh Rajabzadeh

Position

MD, Resident of Obstetrics and Gynecology.

Other areas of specialty/work**Street address**

Shariati Hospital, St. shahid Naser- Bandar Abbas

City

Bandar Abbas

Postal code**Phone**

+98 76 3333 7104

Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary**

empty