

# 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  $\geq 34$  weeks, premature rupture of membranes, Chorioretiniti, 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*