Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparing the efficacy of 17a hydroxyprogesterone caproate (proluton) versus vaginal progesterone (cyclogest) on perinatal outcome in high risk patients who undergo cerclage

Protocol summary

Study aim

The aim of study was to o compare the effectiveness of 17 alpha hydroxyprogesterone caproat with vaginal progesterone on perinatal outcome.

Design

A randomized, clinical trial with a parallel group design of 58 participants was conducted. Simple randomisation was applied using table of random numbers. Accordingly participants were divided in group A or B.

Settings and conduct

Eligible women referring to Khalij-e-Fars hospital undergo cerclage were allocated to study using table of random number after signing the consent form. Each participants received intervention based on their group. Intervention continued till 36 weeks of pregnancy. Then each participants was followed up by phone contact till 28 days after their delivery. Data were collected and analyzed.

Participants/Inclusion and exclusion criteria

Participants were pregnant women with singleton pregnancy at age of 16-22 weeks of pregnancy with the history of more than 2 previous preterm birth.

Intervention groups

Group A received an intra mascular 250 mg of 17 alpha hydroxyprogesterone caproat (proluton from Bayer company) weekly and group B received 200 mg of vaginal progesterone supp (cyclogest from Actavis company) right after cercelage till 36 weeks of pregnancy.

Main outcome variables

The main outcome of study was the incidence of preterm labor. The second outcomes were as follow: Mode of birth, gestational age at the time of delivery, weight of newborn, apgar of newborn, incidence of newborn respiratory distress syndrome and sepsis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181107041585N4**
Registration date: **2020-07-10, 1399/04/20**
Registration timing: **retrospective**

Last update: **2020-07-10, 1399/04/20**
Update count: **0**

Registration date

2020-07-10, 1399/04/20

Registrant information

Name

Fatemeh Darsareh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3355 4515

Email address

famadarsareh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

2017-05-10, 1396/02/20

Actual recruitment end date

2018-02-25, 1396/12/06

Trial completion date

2018-08-23, 1397/06/01

Scientific title
Comparing the efficacy of 17a hydroxyprogesterone caproate (proluton) versus vaginal progesterone (cyclogest) on perinatal outcome in high risk patients who undergo cerclage

Public title
Effect of proluton and cyclogest on perinatal outcome
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
History of more than two previous preterm birth less than 34 weeks Singleton pregnancy Cervical length less than 25 mm based on latest vaginal sonography
Exclusion criteria:
Fetal anomaly Uterine cramp at the time of study Vaginal bleeding at the time of study Preterm rupture of membrane Allergy to hormonal therapy
Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **58**
Actual sample size reached: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using a table of random numbers
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Shafa alley, Hormozgan University of Medical Sciences
City
Bandar Abbas
Province
Hormozgan
Postal code
7919693116
Approval date
2018-03-25, 1397/01/05
Ethics committee reference number
IR.HUMS.REC.1397.052

Health conditions studied

1

Description of health condition studied
Preterm birth
ICD-10 code
060
ICD-10 code description
Onset (spontaneous) of labour before 37 completed weeks of gestation

Primary outcomes

1

Description
Incidence of preterm birth
Timepoint
After 34 weeks of pregnancy
Method of measurement
Observational

Secondary outcomes

1

Description
Gestational age at the time of delivery
Timepoint
At the time of delivery
Method of measurement
Clinical patient record

2

Description
Mode of delivery
Timepoint
At the time of delivery
Method of measurement
Clinical patient record

3

Description
Newborn weight
Timepoint
Immediately after delivery
Method of measurement
Clinical patient record

4

Description

Newborn apgar

Timepoint

Immediately after delivery

Method of measurement

Newborn clinical record

5

Description

incidence of newborn respiratory distress syndrome

Timepoint

At birth and 28 days after birth

Method of measurement

Newborn clinical record

6

Description

Incidence of newborn sepsis

Timepoint

At birth and 28 days after birth

Method of measurement

Newborn clinical record

Intervention groups

1

Description

Intervention group: 250 of 17 alpha hydroxyprogesterone caproat weekly immediately after cercelag procedure till 36 weeks of pregnancy

Category

Treatment - Drugs

2

Description

Intervention group: 400 mg of vaginal progestron daily immediately after cercelag procedure till 36 weeks of pregnancy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalij-e-fars hospital

Full name of responsible person

Amene Ranjbar

Street address

Khalij-e-fars hospital, Pardis Blvd

City

Bandar Abbas

Province

Hormozgan

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7918796758

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+98 76 3367 0285

Email

ranjbar662@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hormozgan University of Medical Sciences

Full name of responsible person

Teamur Aghamolei

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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

Vice chancellor for research, Hormozgan 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

Hormozgan University of Medical Sciences

Full name of responsible person

Amene Ranjbar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Hormozgan University of Medical Sciences
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Associate professor
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Person responsible for updating data

Contact
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Fatemeh Darsareh
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Midwife
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available