Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Studying the effects of ascorbic acid on serum level of unconjugated estriol and its relationship in prevention of preterm premature rupture of membrane

Protocol summary

Summary

The purpose of this study is to check the effect of ascorbic acid on serum level of unconjugated estriol and its relationship on preterm premature rupture of membranes. In this double-blind clinical trial, 60 pregnant women with gestational age 18 weeks who were at the risk of PPROM were companies. Of those pregnant women with a history of surgery on the uterus and a history of cesarean section and were inoculated with a history of pregnancy, were excluded. Patients were divided in to intervention and control groups randomly. 250 mg of vitamin C supplement was prescribed to the intervention group and placebo prepared with apparent drug profile as the same dose and frequency of intervention' s drug (twice daily) was prescribed to control group. Treatment duration was to 28 weeks of gestational age. At 28 weeks gestation serum level of unconjugated estriol was measured by ELIZA method. And results in both groups were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012083580N3**
Registration date: **2011-04-05, 1390/01/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-05, 1390/01/16

Registrant information

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Name of organization / entity

Hamadan University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences and Health Services

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effects of ascorbic acid on serum level of unconjugated estriol and its relationship in prevention of preterm premature rupture of membrane

Public title

Effect of ascorbic acid in prevention of preterm premature rupture of membrane

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational age 18 weeks who are suspicious of PPROM. Exclusion criteria: 1- Lack of follow up patients 2- Lack of

cooperation of patients in taking the drug and placebo in time 3- History of surgery on uterus 4- History of cesarean section 5- Experience of artificial insemination pregnancy 6- Smoking 7- Short cervix

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences and Health Services

Street address
Hamedan university of medical science, in front of Mardom Park, Pazhohesh crossroads, Hamedan

City
Hamedan

Postal code
65177_89975

Approval date
2010-10-06, 1389/07/14

Ethics committee reference number
17-5-3-1

Health conditions studied

1

Description of health condition studied
PPROM

ICD-10 code
o42.9

ICD-10 code description
Premature rupture of membranes, unspecified

Primary outcomes

1

Description
Unconjugated estriol

Timepoint
Is measured once.

Method of measurement
special laboratory kit

2

Description
Frequency of preterm premature rupture of membranes

Timepoint
10 weeks after taking drug and plecebo

Method of measurement
questionnaire

Secondary outcomes

1

Description
Complications after delivery

Timepoint
be assessed after delivery

Method of measurement
questionnaire

Intervention groups

1

Description
250 mg vitamin C supplement was given to intervention group twice a day. (500 mg daily) Patients were taking this supplement from 18 to 28 weeks of pregnancy.

Category
Prevention

2

Description
Placebo which was produced with apparent drug profile of intervention group with the same frequency (twice a day) was prescribed to control group. Patients were taking placebo from 18 to 28 weeks of pregnancy.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Obstetrics and Gynecology Hospital

Full name of responsible person

Street address

City

Hamedan

2

Recruitment center
Name of recruitment center
Sheikhorayis clinic
Full name of responsible person
Street address
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hamedan University of Medical Sciences and Health Services
Full name of responsible person
Ms. Zhila Ahmadkhani
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Hamedan Medical university, in front of Mardom Park, Pazhohesh crossroads, Hamedan
City
Hamedan
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, Hamedan University of Medical Sciences and Health Services
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

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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