

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 PPRM 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

Name

Mehrangiz Zamani

Name of organization / entity

Hamadan University of Medical sciences

Country

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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 PPRM. 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 placebo

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

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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, 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

Contact

Name of organization / entity

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Full name of responsible person

Dr. Lavasani

Position

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Other areas of specialty/work

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Assistant Professor of Obstetrics and Gynecology

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Other areas of specialty/work

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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