

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of progesterone in patients with premature rupture of membranes

Protocol summary

Summary

The aim of this study is the effect of progesterone in patients with premature rupture of membranes (PROM) and prolongs the incubation period at Al-Zahra hospital. Patients were randomly divided in two cases and controls groups (Each group consisted of 60 patients and in three age groups of 26-28 weeks/ 28-30 weeks/ 30-32 weeks and in each and in each age group studied 20 patients). Gestational age of pregnant women between 26 to 32 weeks with PROM diagnosis by having informed consent will be included in the study. In the cases of fetal abnormalities that can affect fetal growth, preeclampsia and being in the active phase of labor patients will be excluded. The first group received progesterone (400 mg intra-vaginal progesterone) and the second group did not receive progesterone. Treatment will continue to 34 weeks or to delivery. At baseline, patients were admitted in the maternity unit for 12 to 24 hours. All patients (cases and controls) will treated with Antibiotics and Betamethasone and the case group each night will receive rectal suppository progesterone and at least once a day twice a week will treated with BPP and NST respectively and chorioamnionitis will daily examined. All patients have been hospitalized until delivery or up to the 34th week of pregnancy and lung maturation is checked and do not be treated with Tocolysis. In all patients PROM duration and onset of labor or termination planned at 34 weeks of pregnancy, puerperal fever, incidence of chorioamnionitis, birth weight, apgar 1 and 5, number of days of ventilated baby and neonatal deaths are recorded. Patients after discharge from the hospital twice a week for 6 weeks will be followed up by phone in terms of symptoms: Fever, chills, and foul-smelling purulent discharge from the vagina, abdominal pain and tenderness, shortness of breath and in case of abnormal symptoms patients will be seen in person at Al-Zahra Hospital.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512077676N4**

Registration date: **2016-04-06, 1395/01/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-06, 1395/01/18

Registrant information

Name

Simin Taghavi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1553 9161

Email address

taghavisit@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Tabriz University of Medical Sciences

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2017-02-08, 1395/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of progesterone in patients with premature rupture of membranes

Public title

The effect of progesterone in patients with premature rupture of membranes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with gestational age between 26 to 32 weeks with premature rupture of membranes (PROM); signing informed consent. Exclusion criteria: fetal abnormalities; genetic abnormalities that can affect fetal growth that have been checked by ultrasound at 18 to 20 weeks and 28 to 32 weeks. Along with trisomy screening marker with double or quad marker; precambrian patients; chronic high blood pressure; overt diabetes; pregnancy-related diabetes; detachment; prolapsed umbilical cord; chorioamnionitis; gestational age over 32 weeks (because there isn't sufficient time to study the effects of progesterone); patient who have had a rupture of the membranes after 36 hours; patient who are in active phase.

Age

From **15 years** old to **48 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description**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 Tabriz University of Medical Sciences

Street address

Ethics Committee Of Tabriz University Of Medical Sciences; Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Postal code**Approval date**

2016-02-04, 1394/11/15

Ethics committee reference number

TBZMED.REC.1394.1008

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

Premature rupture of membranes, labour delayed by therapy

ICD-10 code

O42

ICD-10 code description

Premature rupture of membranes, labour delayed by therapy

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

Lengthening the interval between the pre-term delivery runny

Timepoint

Daily

Method of measurement

Physical examination

Secondary outcomes**1****Description**

Improving Perinatal Outcomes

Timepoint

Follow baby daily until discharge

Method of measurement

Physical examination

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

Intervention group : progesterone (400 mg a daily intravaginal

Category

Treatment - Drugs

2**Description**

Control group: routine treatment includes injections of betamethasone 12 mg of progesterone administered every 12 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Simin Taghavi

Street address

South Alzahra Hospital ; Artesh Street; Bagh shomal
Crossroads

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology
University of Medical Sciences

Full name of responsible person

Dr.Alireza Rashidi

Street address

Golgasht Street; Central Building Number Two; third
floor

City

Tabriz

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 and Technology 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

Tabriz University of medical Sciences

Full name of responsible person

Dr.Simin Taghavi

Position

Professor of obstetrics and gynecology specialist

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