

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

To investigate the possible effect of Progesterone Supp on cytokines endocervical concentration of women at risk of abortion

Protocol summary

Summary

To Investigate the possible effect of progesterone Supp on cytokines endocervical concentration of women at risk of abortion. In a clinical randomized trial of 100 prime-gravid women at risk of abortion less than 20 weeks of gestation, cervical fluids were collected. Pregnant women with sign and symptoms of threatened abortion like bleeding, abdominal pain and induction of cervical secretion were included in this study. Lack of satisfaction, hypertension and avoidance of participating in the study were considered as exclusion criteria. Endocervical concentration of inflammatory cytokines were analyzed before and after progesterone treatment for evaluation of cytokine concentration. Wilcoxon and Mann-Whitney tests were employed for statistical analysis. χ^2 and Student's t tests were used if needed. The cytokines concentration were determined with standard Eliza kits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012035294N1**

Registration date: **2012-03-17, 1390/12/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-17, 1390/12/27

Registrant information

Name

Pouya Javadian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

hantoushzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2006-06-22, 1385/04/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To investigate the possible effect of Progesterone Supp on cytokines endocervical concentration of women at risk of abortion

Public title

Progesterone effect on threatened abortion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women less than 20 weeks of gestation with sign and symptoms of threatened abortion like bleeding, abdominal pain and induction of cervical secretion were included in this study; Exclusion criteria: Lack of satisfaction, hypertension and avoidance of participating in the study were considered as exclusion criteria.

Age

From **16 years** old to **44 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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 in Research committee in Hamdan University of Medical Sciences

Street address

Medical University of Hamadan, Bouali Sina Street

City

Hamadan

Postal code**Approval date**

2011-01-12, 1389/10/22

Ethics committee reference number

1-3-10-5-25-12

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

abortion

ICD-10 code

P01.8

ICD-10 code description

Fetus and newborn affected by other maternal complications of pregnancy Spontaneous abortion, fetus

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

incidence of abortion

Timepoint

at the end of study

Method of measurement

due to definition, fetal weight less than 500 grams and delivery before 20 weeks

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

study the inflammatory cytokines of cervix

Timepoint

before and after treatment

Method of measurement

special kits & Eliza

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

Placebo suppository

Category

Placebo

2**Description**

Progesterone suppository 400 mg twice daily for a week

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali-e-Asr Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr.Sedigheh Hantoushzadeh

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr.Akbar Fotouhi

Street address

Vice chancellor for research, Headquarter for Tehran University of Medical Sciences, On the Corner of Keshavarz Blvd. and Qods Street, Keshavarz Blvd., Vali-e-Asr Square, Tehran, Iran.

City
Tehran

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, Tehran University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity
Vice chancellor for research, Imam Khomeinei Hospital

Full name of responsible person
Dr.Akbar Fotouhi

Street address
Vali-e-Asr Hospital, Tehran University of Medical Sciences, Bagher Khan Street, Shahid Chamran High way

City
Tehran

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, Imam Khomeinei Hospital

Proportion provided by this source

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
Vali-e-Asr Hospital, Tehran University of Medical Sciences

Full name of responsible person
Dr.Sedigheh Hantoushzadeh

Position

Associate Professor of Tehran University of Medical Sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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General Praticitioner

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