

# 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.  $\chi^2$  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

+98 21 8826 3641

###### 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**

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

**City**  
Tehran

**Postal code**

**Phone**  
+98 912 127 1209

**Fax**

**Email**  
hantoushzadeh@tums.ac.ir

**Web page address**

### **Person responsible for scientific 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 Professore of Tehran University of Medical Sciences

**Other areas of specialty/work**

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

**City**  
Tehran

**Postal code**

**Phone**  
+98 912 127 1209

**Fax**

**Email**  
hantoushzadeh@tums.ac.ir

**Web page address**

### **Person responsible for updating data**

#### **Contact**

**Name of organization / entity**  
Vali-e-Asr Hospital, Tehran University of Medical Sciences

**Full name of responsible person**  
Dr.Pouya Javadian

**Position**  
General Praticitioner

**Other areas of specialty/work**

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

**City**  
Tehran

**Postal code**

**Phone**

+98 21 6658 1617

**Fax**

**Email**

pouyajavadian@yahoo.com

**Web page address**

**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*