

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effect of autologous conditioned serum on endometrial thickness and fertility rate of patients

#### Protocol summary

##### Study aim

The effect of autologous conditioned serum on endometrial thickness and fertility rate of patients

##### Design

The clinical trial is without the control group, single, not blinded, non-randomized and quasi-experiment before-after design.

##### Settings and conduct

Blood samples will be collected at Valiasr Hospital in Tabriz, autologous conditioned serum will be provided and quality control will be provided. Then the autologous conditioned serum will be injected to the patients and after endometrial thickness reaches 7 mm they will have in vitro fertilization (IVF). Finally, the success of IVF and pregnancy will be assessed using beta-human chorionic gonadotropin ( $\beta$ -hCG) and sonography measurements.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women between the ages of 25-40 years, failed in vitro fertilization (IVF), having a history of infertility, endometrial thickness less than 7 mm  
Exclusion criteria: having a normal pregnancy history and having no infertility problems, having a problem with infertility for reasons other than the inclusion criteria, people with malignancy, people with Asherman's Disease

##### Intervention groups

Women with inclusion criteria will be administered autologous conditioned serum on days 10-9 and 12-11 days and will be injected intrauterine.

##### Main outcome variables

The effect of autologous conditioned serum on endometrial thickness; The effect of autologous conditioned serum on fertility rate of patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160422027520N15**

Registration date: **2019-12-03, 1398/09/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-03, 1398/09/12**

Update count: **0**

##### Registration date

2019-12-03, 1398/09/12

##### Registrant information

###### Name

Mehdi Yousefi

###### Name of organization / entity

Department of Immunology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3336 4665

###### Email address

yousefime@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-06, 1398/08/15

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of autologous conditioned serum on endometrial thickness and fertility rate of patients

##### Public title

Increase endometrial thickness with autologous conditioned serum

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Women between the ages of 25-40 years Failed in vitro fertilization (IVF) The availability of individual during the study period Having a history of infertility Endometrial thickness less than 7 mm

##### **Exclusion criteria:**

Having a financial incentive to participate in the study or Participate in another study simultaneously Endometrial thickness more than 7 mm People with malignancy Previous delivery with cesarean section or having a normal pregnancy history Having a history of curettage Having pelvic inflammatory disease (PID) History of radiotherapy at an in the past People with Asherman's Disease

#### **Age**

From **25 years** old to **40 years** old

#### **Gender**

Female

#### **Phase**

1-2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **10**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Single

#### **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**

Tabriz University of Medical Sciences , Daneshgah st, Tabriz

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614766

#### **Approval date**

2019-03-17, 1397/12/26

#### **Ethics committee reference number**

IR.TBZMED.REC.1397.1000

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Infertility due to low endometrial thickness

#### **ICD-10 code**

N80

#### **ICD-10 code description**

Endometriosis

## **Primary outcomes**

### **1**

#### **Description**

The effect of autologous conditioned serum on endometrial thickness

#### **Timepoint**

1 and 4 weeks after autologous conditioned serum injection

#### **Method of measurement**

Using sonography

## **Secondary outcomes**

### **1**

#### **Description**

The effect of processed autologous serum on fertility rate of patients

#### **Timepoint**

1, 4 and 12 weeks after in vitro fertilization (IVF)

#### **Method of measurement**

Using sonography and Serum beta-human chorionic gonadotropin ( $\beta$ -hCG) level assessment by enzyme-linked immunosorbent assay (ELISA) kit

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The consumable material in this study is autologous conditioned serum (ACS) that is obtained by contacting a person's serum with glass beads in a sterile environment. The ACS is manufactured using Standard Kit Company's kits. This is an Iranian company. This product contains growth factors and anti-inflammatory cytokine and will be injected autologously. 10 patients with a history of infertility with less than 7 mm in endometrial thickness will be selected and, after obtaining informed consent, will be referred to the Vali-e-Asr Hospital for autologous conditioned serum injection. Endometrial thickness will be assessed 1 and 4 weeks after preparation and intrauterine injection of

autologous conditioned serum (on days 9-10 and 12-12).  
in vitro fertilization (IVF) will be performed if the  
endometrial thickness exceeds 7 mm. Pregnancy of  
patients up to 12 weeks is monitored by sonography and  
serum beta-human chorionic gonadotropin ( $\beta$ -hCG) level.

**Category**

Treatment - Other

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

Vali-e-asr Hospital, Tabriz

**Full name of responsible person**

Mehdi Yousefi

**Street address**

Vali-e-asr Hospital, El-Goli

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3335 7767

**Email**

mehdi\_yusefi@yahoo.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Yousefi

**Street address**

Tabriz University of Medical Sciences, Golgasht  
Avenue, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3336 4665

**Email**

yousefime@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Yousefi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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Tabriz University of Medical Sciences, Golgasht  
Avenue, Tabriz, Iran

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**Person responsible for scientific  
inquiries****Contact****Name of organization / entity**

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## Person responsible for updating data

### Contact

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Tabriz University of Medical Sciences

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available