

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### Study of injection of follicular fluid into uterine cavity on implantation rate in IVF cycle

#### Protocol summary

##### Summary

The main objective of this study is injection of follicular fluid into uterine cavity on implantation rate in IVF cycle. In a randomized unit-central clinical trial, 68 patients with recurrent implantation failure referring to infertility clinic of Alzahra Hospital, Tabriz, Iran, will be randomly assigned to two groups' case and control. The main inclusion criterion are: FSH levels below mIU / ml 10 and age between 20 to 40 years and the main exclusion criterion are have history of two or more implantation failure in in-vitro fertilization and having endometriosis. Patients were randomly placed in two groups of 55 people. From day 2 or 3 cycles 150 to 300 IU FSH injection and ovulation induction will start. After 6 or 7 cycles, antagonist of GnRH injections administered at a dose of 250 mg daily and 75 to 150 units monogon will be added to the diet 1 to 2 Tablets. After see at least three follicles larger than 18 mm HCG will be injected and then 34 to 36 hours after that, will be done the puncture of ovarian follicles. The follicular fluid of 2 or 3 follicular puncture obtained If that is not tinged with blood, after removal of the oocyte will be centrifuge and collected in a separate tube. After puncture2, ml of the liquid will be injected into the uterus using catheters IUI. In this study, the primary outcome of successful implantation and clinical pregnancy is considered to be a secondary consequence. In the control group method is the same of case without injected follicular liquid.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015021713566N3**

Registration date: **2015-05-29, 1394/03/08**

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

Last update:

Update count: **0**

##### Registration date

2015-05-29, 1394/03/08

##### Registrant information

###### Name

Kobra Hamdi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1554 1221

###### Email address

hamdik@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2015-04-19, 1394/01/30

##### Expected recruitment end date

2016-07-20, 1395/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of injection of follicular fluid into uterine cavity on implantation rate in IVF cycle

##### Public title

Study of injection of follicular fluid into uterine cavity on implantation rate in IVF cycle

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: patients aged 20 to 40 years old; FSH levels below mIU / mL 10; BMI less than 35 kg /m<sup>2</sup>; transfer 2 or 3 embryos Grade A or B; Exclusion criteria: patients with endometriosis; hydrosalpinx; uterine anatomical abnormalities such as myoma; polyps; mullerian anomalies like two horns of the uterus; endocrine disorders such as thyroid disease; PCO and have a history of two or more implantation failure.

## **Age**

From **20 years** old to **40 years** old

## **Gender**

Female

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **110**

## **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**

Tabriz University of Medical Sciences

##### **Street address**

Golgasht Street ,Tabriz University Of Medical Sciences

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2015-05-16, 1394/02/26

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

TBZMED.REC.1394.129

## **Health conditions studied**

### **1**

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

Infertility

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

N97.0

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

Female infertility associated with anovulation

## **Primary outcomes**

### **1**

#### **Description**

Chemical Pregnancy

#### **Timepoint**

Measure B-HCG Sixteen days after injection of HCG

#### **Method of measurement**

BhCG test

### **2**

#### **Description**

Clinical pregnancy ( gestational sac seen by viewing the fetal heart rate and fetal pole

#### **Timepoint**

After positive  $\beta$ hCG

#### **Method of measurement**

Ultrasound

### **3**

#### **Description**

Implantation rates

#### **Timepoint**

Two weeks after a positive pregnancy test

#### **Method of measurement**

Ultrasound

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

In the control group: Antagonist protocol GnRH will be used to stimulate ovulation, HCG may be used to seeing at least three follicles larger than 18 mm. After 34 to 36 hours will puncture of ovarian follicles

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

In the intervention group: Antagonist protocol GnRH will be used to stimulate ovulation, HCG may be used to seeing at least three follicles larger than 18 mm. After 34 to 36 hours will puncture of ovarian follicles. After isolation of the oocyte Part of follicular fluid from the puncture. Will be injected by intrauterine 2 cc of liquid by using IUI catheter after follicle puncture embryo transfer will take place two days after ovarian puncture.

#### **Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Dr. Kobra Hamdi

**Street address**

Alzahra Hospital, South Artesh Ave

**City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for Research,Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Rashidi

**Street address**

Third Floor, Central Building of Number2, Golgasht Street

**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,Tabriz 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. Kobra Hamdi

**Position**

Associate professor

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*