

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of serum and uterine flushing Glycodelin concentrations in reproductive cycles among women with in vitro fertilization failure and fertile controls: A pilot Study.

Protocol summary

Summary

Objectives: Glycodelin is an agent which regulates immunological factors activity. This is required in implantation window. The present study was conducted to compare glycodelin concentrations in blood and uterine flushing samples obtained from women with in vitro fertilization failure and fertile controls. Study design: Twenty infertile women with in vitro fertilization failure and twenty fertile women in control group, phase 2, single center, non-blinded, non-randomized pilot study. Setting and conducts: Women based on inclusion criteria will be divided in two groups. Patients and physicians, informed and aware of the intervention. Injection of normal saline into the uterus and examination the return uterine fluid about glycodelin concentrations will be done on day 21 to 22 of the menstrual cycle in both groups. At the same time, blood sampling will be taken for evaluation of serum glycodelin concentrations in both groups. Inclusion criteria: Forty women aged 20 to 40 years, in vitro fertilization failure in half of them (at least 2 cycles of in vitro fertilization failure), lack of polyps or uterine fibroids. Exclusion criteria: Presence of uterine polyps or fibroids, history of hormone use in the past two months, active vaginal infection. Intervention: Injection of normal saline into the uterus on day 21 to 22 of the menstrual cycle and examination the return uterine fluid about glycodelin concentrations. At the same time, blood sampling will be taken for evaluation of serum glycodelin concentrations in patients with in vitro fertilization failure and fertile control group. Primary outcome: Glycodelin concentrations in serum and uterine flushing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082120408N5**

Registration date: **2016-10-05, 1395/07/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-10-05, 1395/07/14

Registrant information

Name

Robabeh Taheripanah

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Tehran, Iran.

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University
of Medical Sciences

Expected recruitment start date

2016-11-30, 1395/09/10

Expected recruitment end date

2017-01-31, 1395/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of serum and uterine flushing Glycodelin concentrations in reproductive cycles among women with in vitro fertilization failure and fertile controls: A pilot Study.

Public title

Effects of Glycodelin on women with implantation failure

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Forty women aged 20 to 40 years; in vitro fertilization failure in half of them (at least 2 cycles of in vitro fertilization failure) ; lack of polyps or uterine fibroids. Exclusion criteria: Presence of uterine polyps or fibroids; history of hormone use in the past two months; active vaginal infection.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Non-blinded, non-randomized pilot study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences.

Street address

220 Plaque, Third floor, Shahid Beheshti University of Medical Sciences, Velenjak Ave, Chamran high way, Tehran

City

Tehran

Postal code

1393944176

Approval date

2011-06-26, 1390/04/05

Ethics committee reference number

102

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

Noninflammatory disorders of female genital tract

ICD-10 code

N98.9

ICD-10 code description

Complication associated with artificial fertilization, unspecified

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

Serum glycodelin concentrations

Timepoint

On day 21-22 of menstrual cycles.

Method of measurement

Laboratory kits.

2**Description**

Uterine flushing glycodelin concentrations

Timepoint

On day 21-22 of menstrual cycles

Method of measurement

Laboratory kits

Secondary outcomes

empty

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

Intervention 1: Injection of normal saline into the uterus on day 21 to 22 of the menstrual cycle (intrauterine insemination catheter, Cook Company, USA) and examine the uterine flushing and blood sampling for evaluation of glycodelin concentrations.

Category

Diagnosis

2**Description**

Intervention 2: Injection of normal saline into the uterus on day 21 to 22 of the menstrual cycle (intrauterine insemination catheter, Cook Company, USA) and examine the uterine flushing and blood sampling for evaluation of glycodelin concentrations.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospitals

Full name of responsible person

Marzieh Zamaniyan

Street address

233 plaque, Third floor, IVF ward, Taleghani Hospital,
Velenjak Ave, Chamran high way, Tehran

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2

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Marzieh Zamaniyan

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67 plaque, second floor, Obstetrics and Gynecology
ward, Imam Hossein Hospital, Shahid madani Ave,
Imam Hossein Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Sciences, Tehran, Iran.

Full name of responsible person

Zahra Sadeghzadeh

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262 plaque, Third Floor, Sahid Beheshti University of
Medical Sciences, Velenjak Ave, Chamran high way,
Tehran

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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, Shahid Beheshti University
of Medical Sciences, Tehran, Iran.

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**

Reproductive and Infertility Health Research Center,
Shahid Beheshti University of Medical Sciences,

Full name of responsible person

Marzieh Zamaniyan

Position

Assistant professor, M.D.

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

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Person responsible for updating data

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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