

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Investigating the effect of midwifery-designed training on perceived anxiety and pain intensity from hysterosalpingography in infertile women

Protocol summary

Study aim

Determining the effect of the educational program designed by midwives on the level of anxiety and perceived pain intensity of performing

Design

Clinical trial with control and intervention group, single groups, single-blind, randomized, phase 2 on 86 patients, random number table was used for randomization.

Settings and conduct

This study is conducted on infertile women who are candidates for HSG, referring to the imaging department of Royan Research Institute. After admission, people are placed in intervention and control groups based on even and odd days. For blinding, none of the subjects were told which group they were in.

Participants/Inclusion and exclusion criteria

Entry requirements: Infertile women volunteer for Hysterosalpingography Age range 20-49 years Iranian nationality Ability to speak Persian Literacy for reading and writing Not suffering from known anxiety disorders or other mental illnesses affecting anxiety under treatment Failure to enter: History of (HSG) Early diagnosis of tubal and uterine lesions that cause severe pain in a person.

Intervention groups

In the intervention group, after accepting and obtaining informed consent, the people of this group are offered a face-to-face training program where people can ask their questions to the trainer. People complete the relevant questionnaires after each stage. In the control group, after accepting and providing an explanation about the research, people complete the questionnaires and tools with informed consent. And no educational intervention is done for them.

Main outcome variables

Reduction of anxiety and pain perceived by women undergoing (HSG). Decrease heart rate and blood pressure of people Increasing people's awareness of (HSG)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150905023897N6**

Registration date: **2023-05-16, 1402/02/26**

Registration timing: **prospective**

Last update: **2023-05-16, 1402/02/26**

Update count: **0**

Registration date

2023-05-16, 1402/02/26

Registrant information

Name

Dr. Shahideh Jahanian Sadatmahalleh

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4826

Email address

shahideh.jahanian@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-20, 1402/02/30

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of midwifery-designed training on perceived anxiety and pain intensity from hysterosalpingography in infertile women

Public title

Investigating the effect of midwifery-designed training on perceived anxiety and pain intensity from hysterosalpingography in infertile women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Voluntary infertile women Age 20-49 years Iranian nationality Ability to speak Persian Literacy Not suffering from known anxiety disorders or other mental illnesses affecting anxiety under treatment No history of HSG People who are inclined to participate in the study.

Exclusion criteria:

Patient withdrawal from the study Failure to complete the HSG process for any reason Presence of tubal or uterine lesions, such as cervical stenosis, which cause "severe pain" in the HSG process

Age

From **20 years** old to **49 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to perform randomization, the researcher put 4 balls, including 2 white balls: intervention and control, and 2 black balls: even day and odd day, which he named in this way and put them in a container and asked someone to pick up two different colors. This is the way that those balls were selected: even day and intervention, odd day and control. In this way, people who visit on even days are in the intervention group, and people who visit on odd days are in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

After admission, people are randomly assigned to each of the intervention and control groups. None of them were informed about their group and they just trained about the stages what should they do.

Placebo

Not used

Assignment

Single

Other design features

In this research, it should be measured the level of target group's knowledge about hysterosalpingography. To achieve this, a questionnaire should be prepare by researcher whose validity and reliability are also

measured.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr bridg, Ale ahmad high way,Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۱۷۱۳۱۱۶

Approval date

2022-10-03, 1401/07/11

Ethics committee reference number

IR.MODARES.REC.1401.144

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97.1

ICD-10 code description

Female infertility of tubal origin

Primary outcomes

1

Description

The patient's heart rate

Timepoint

Heart rate measurement at the beginning of the study (before the intervention), half an hour before the intervention, immediately and half an hour after the intervention

Method of measurement

Pulse meter

2

Description

The patient's blood pressure

Timepoint

Blood pressure measurement at the beginning of the study (before the intervention), half an hour before the intervention, immediately and half an hour after the intervention

Method of measurement

Sphygmomanometer

3

Description

Patients' awareness of hysterosalpingography

Timepoint

Measuring the patient's knowledge about hysterosalpingography at the beginning of the study (before the intervention), half an hour before the intervention, immediately and half an hour after the intervention

Method of measurement

Hysterosalpingography awareness questionnaire (made by a researcher)

4

Description

Patient anxiety

Timepoint

Measuring the patient's anxiety at the beginning of the study (before the intervention), half an hour before the intervention, immediately and half an hour after the intervention

Method of measurement

State Trait Anxiety Inventory (STAI)

5

Description

Perceived pain from the hysterosalpingography procedure

Timepoint

Measurement of perceived pain in the initial study (before the intervention), half an hour before the intervention, treatment and half an hour after the intervention

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Control group: After accepting people according to the entry criteria, and obtaining informed consent, people are randomly assigned to the control and intervention groups. The control group does not receive any educational or counseling intervention and only the center's routine admission is done for them. The other mentioned cases are the same in both groups. including questionnaires and timings necessary to measure the variables.

Category

Behavior

2

Description

Intervention group: After accepting people according to the entry criteria, and obtaining informed consent, people are randomly assigned to control and intervention groups. People in the intervention group receive educational items and counseling (educational intervention) before performing hysterosalpingography.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Shahideh Jahanian Sadatmahalleh

Street address

East Hafez St, North Bani Hashem St, Resalat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1665659911

Phone

+98 21 2356 2000

Fax

+98 21 2230 6481

Email

info@royaninstitute.org

Web page address

<https://www.royan.org>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shahideh Jahanian Sadatmahalleh

Street address

Jalal E Al Ahmad

City

Tehran

Province

Tehran

Postal code

۱۴۱۱۷۱۳۱۱۶

Phone

+98 21 8800 6544

Fax

+98 21 8800 6544

Email

pres@modares.ac.ir

Web page address

https://www.modares.ac.ir

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

Yes

Title of funding source

Tarbiat Modares University

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**

Tarbiat Modares University

Full name of responsible person

Shahideh Jahanian Sadatmahalleh

Position

دانشیار

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Jalal E Al Ahmad

City

Tehran

Province

Tehran

Postal code

141173116

Phone

+98 21 8288 4826

Fax

+98 21 8288 4826

Email

shahideh.jahanian@modares.ac.ir

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

Tarbiat Modares University

Full name of responsible person

Shahideh Jahanian Sadatmahalleh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Jalal E Al Ahmad

City

Tehran

Province

Tehran

Postal code

۱۴۱۱۷۳۱۱۶

Phone

+98 21 2230 6480

Fax

+98 21 8288 4826

Email

shahideh.jahanian@modares.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Shahideh Jahanian Sadatmahalleh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Jalal E Al Ahmad

City

Tehran

Province

Tehran

Postal code

141173116

Phone

+98 21 2230 6480

Fax

+98 21 8288 4826

Email

shahideh.jahanian@modares.ac.ir

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

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main outcome of the study

When the data will become available and for how long

2023

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Use for additional research in the future

From where data/document is obtainable

Email Addressing Responsible for study

What processes are involved for a request to access data/document

Submit a request to study and follow up

Comments