Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of the Rose Damascena aromatherapy on stress, anxiety and the outcome of conception in women candidate for Intracytoplasmic sperm injection (ICSI)

Protocol summary

Study aim

Determining the effect of the scent of the rose flower on stress, anxiety and the result of conception of women candidates for ICSI

Design

The clinical trial has two experimental and control groups with parallel groups, randomized on 62 women candidates for ICSI at the stage of embryo transfer into the uterus.

Settings and conduct

This study is an open-label randomized controlled clinical trial. The sampling center is Arash Women's Comprehensive Hospital. Women will be included in the study if they have moderate and severe stress and anxiety. After the implementation of the intervention and immediately before going to the operating room, the DASS21 questionnaire will be completed in both test and re-control groups, and the level of stress and anxiety in the two groups will be compared before and after the intervention. Two weeks later, we will check the results by the B-HCG test.

Participants/Inclusion and exclusion criteria

Inclusion primary infertility aged 20 to 40 years infertility for at least 3 years moderate and severe stress and anxiety based on the DASS21 questionnaire. Exit Using perfume Allergy to essential oils History of migraine Disturbance in smell severe mental and physical diseases Occurrence of severe stressful factors in the last 6 months The need to use to reduce stress and anxiety Addiction to tobacco, drugs and alcohol

Intervention groups

One hour before going to the embryo transfer room, aromatherapy and placebo are performed in the groups, and the level of stress and anxiety in the groups is compared before and after the intervention. Two weeks later, we will check the B HCG test.

Main outcome variables

1- Aromatherapy with the scent of roses and placebo on moderate or severe stress and anxiety, which is measured and compared with the DASS 21 questionnaire. 2- Pregnancy result is determined 2 weeks after aromatherapy and embryo injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240609062051N1**
Registration date: **2024-06-16, 1403/03/27**
Registration timing: **prospective**

Last update: **2024-06-16, 1403/03/27**
Update count: **0**

Registration date

2024-06-16, 1403/03/27

Registrant information

Name

Saeideh Baghaei Barjini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 1458

Email address

s.baghaei03@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-22, 1403/04/02

Expected recruitment end date

2024-09-23, 1403/07/02

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the Rose Damascena aromatherapy on stress, anxiety and the outcome of conception in women candidate for Intracytoplasmic sperm injection (ICSI)

Public title
Investigating aromatherapy with the scent of roses in stress and anxiety in the treatment of infertility and pregnancy outcome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Women with primary infertility aged 20 to 40 years Having at least 3 years of infertility history. Women with moderate and severe stress and anxiety based on the DASS21 questionnaire
Exclusion criteria:
Use of perfume during operation Having a degree in psychology and participating in psychology sessions Allergy to herbal essential oils History of migraines and severe headaches Inhalation and smell disorders Suffering from severe mental and physical illnesses Occurrence of severe stressors in the last 6 months (death of first-degree relatives, driving accidents) The need to use other pharmacological and non-pharmacological methods to reduce stress and anxiety Addiction to tobacco, drugs and alcohol and the need to receive them
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: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method is accessible and based on the study entry and exit criteria. In this way, after obtaining written consent from the samples, people are assigned to 2 intervention and control groups using block random allocation method and blocks of 4. Blocks are selected randomly and by placement.By using this method, it can be ensured that an equal number of participants will enter the experimental and control groups in consecutive time intervals. In order to prevent the possibility of the effect of the aroma spread in the air on the people of the studied groups, the department manager will be requested to place the studied samples in a separate room based on randomization and the same type of intervention received. For blocks of 4, six modes are considered as follows: 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences
Street address
Kamalvand
City
Khorramabad
Province
Lorestan
Postal code
6813833946
Approval date
2024-05-21, 1403/03/01
Ethics committee reference number
IR.LUMS.REC.1403.090

Health conditions studied

1

Description of health condition studied
Stress and anxiety of women candidates for intracytoplasmic sperm injection at the stage of embryo injection
ICD-10 code
F40.8
ICD-10 code description
Other phobic anxiety disorders

2

Description of health condition studied
Pregnancy result two weeks after embryo injection and aromatherapy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The stress and anxiety score is based on the DASS 21 questionnaire, which is measured one hour before embryo injection and aromatherapy with the scent of roses or placebo and immediately before injection and after aromatherapy.

Timepoint
Before and after aromatherapy with the scent of roses and placebo

Method of measurement
with DOSS 21 questionnaire

2

Description
The result of pregnancy, which is measured by beta HCG two weeks after the injection of the embryo into the uterus.

Timepoint
Two weeks after intrauterine embryo injection

Method of measurement
اندازه‌گیری مقدار بتا اچ سی جی در خون دو هفته بعد از تزریق جنین ورایحه درمانی است.The amount of beta HCG in the blood is measured two weeks after embryo injection and aromatherapy.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1 hour before the injection of the embryo into the uterus, first fill the DAS 21 questionnaire and if the stress and anxiety were moderate or severe. Pour 3 drops of essential oil of 10 roses on a cotton ball in a zipped bag and ask the research unit in the intervention group to inhale for 10 minutes at a distance of 7 cm from his nose, and 1 hour later before the embryo injection, we measure the level of stress and anxiety with the DAS 21 questionnaire and with We compare before intervention.

Category
N/A

2

Description
Control group: 1 hour before the intrauterine injection of the fetus, first fill the DAS 21 questionnaire and if the stress and anxiety were moderate or severe. Pour 3 drops of distilled water on a cotton ball that is in a zippered bag and we ask the research unit in the control group to inhale for 10 minutes at a distance of 7 cm from his nose, and 1 hour later before the embryo injection, we measure the level of stress and anxiety with the DAS 21 questionnaire and before the intervention We compare.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Arash Hospital

Full name of responsible person
Saeideh Baghaei Barjini

Street address
162 Alley. Baghdarnia Street. Resalat

City
Tehran

Province
Tehran

Postal code
67395858

Phone
+98 21 7788 3283

Fax

Email
hosp_arash@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Ashraf Moeini

Street address
162 Alley. Baghdarnia Street. Resalat

City
Tehran

Province
Tehran

Postal code
1653915981

Phone
+98 21 7788 3283

Email
ashraf.moieni@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Saeideh Baghaei Barjini

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No 1. Mohajer Alley. Behboodi Street. Sattarkhan Street

City

Tehran

Province

Tehran

Postal code

1598116539

Phone

+98 21 7788 3283

Email

S.baghaei03@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr. Mozhan masoudi

Position

University assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Kamalvand - Lorestan University of Medical Sciences

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3312 0165

Email

masoudi.mozh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Saeideh Baghaei Bargini

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No 1. Mohajer Alley. Behboodi Street. Sattarkhan Street

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3283

Fax

+98 21 7788 3196

Email

s.baghaei@gmail.com

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