

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### The effect of husband's support on maternal anxiety and stress of pregnant women undergoing the amniocentesis

#### Protocol summary

##### Study aim

Comparison of the mean stress and anxiety in two groups of pregnant women with and without spousal support during amniocentesis

##### Design

A clinical trial with a control group, in parallel groups, one-way blind, randomized is performed on 90 patients. Randomization is done using double blocks.

##### Settings and conduct

Two perinatology centers in Mashhad in Imam Reza and Umm Al-Banin hospitals In the intervention group, a briefing session (support for pregnant women) is held for husbands before amniocentesis. Maternal stress and anxiety are measured in three stages in the control and intervention groups, and correction is performed for statistical data analysts.

##### Participants/Inclusion and exclusion criteria

Minimum literacy Gestational age 15 to 18 weeks  
Willingness to participate in the study The desire for his wife to be present at his bedside during amniocentesis  
No entry: Couple dissatisfaction History of mental illness  
Reproductive assistance methods

##### Intervention groups

For pregnant women's wives, a face-to-face briefing session will be held for 45 to 60 minutes, two to seven days before the amniocentesis, which will provide information on the need and method of amniocentesis, its complications, its consequences for stress, and Anxiety in pregnant women and the effect of their presence and support on their husbands in reducing their stress and anxiety levels. During this process, after amniocentesis care, Men are asked to be with their wives and provide the necessary support for them. for the Control group, routine care will be performed.

##### Main outcome variables

Anxiety and stress levels of amniocentesis pregnant women included in the study before the intervention, before and after amniocentesis will be completed with standard Spielberger Anxiety Inventory, DASS-21 Anxiety

and Stress and Depression Inventory and self-made questionnaire of spouse support by research units. became.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220423054626N1**

Registration date: **2023-03-02, 1401/12/11**

Registration timing: **prospective**

Last update: **2023-03-02, 1401/12/11**

Update count: **0**

##### Registration date

2023-03-02, 1401/12/11

##### Registrant information

##### Name

Fatemeh Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 930 472 9909

##### Email address

salehif951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-12, 1401/12/21

##### Expected recruitment end date

2023-04-10, 1402/01/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of husband's support on maternal anxiety and stress of pregnant women undergoing the amniocentesis

**Public title**  
The efficacy of husband's support on maternal anxiety and stress of pregnant women undergoing the amniocentesis

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Gestational age: 15-18 weeks Ability of reading and writing couples Satisfaction for participation in the project candidate of amniocentesis Score 20-59 from the Spielberger Anxiety Questionnaire on the Manifest's Anxiety Scale (mild to moderate) Obtain a stress score greater than 14 and less than 26 from the DASS-21 questionnaire  
**Exclusion criteria:**  
History of infertility and Pregnancy with assisted reproductive techniques History of amniocentesis Taking psychiatric drugs History of mental illness and hospitalization due to mental health problems for at least the last 6 months

**Age**  
From **18 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: **90**

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

**Randomization description**  
Method: Randomized blocking based on PASS\_11 software with 4 blocks Random unit: All pregnant mothers who meet the study entry criteria. Tools: Blocked closed packets based on software Concealment: The sealed packets of the people that have been prepared using the PASS\_11 software are selected at the same time as the mother enters the study. Based on the assigned number in each group, the people are assigned to two intervention and control groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Those who evaluate the outcome

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Ebne sina

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948974

#### Approval date

2021-10-26, 1400/08/04

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1400.095

## Health conditions studied

### 1

#### Description of health condition studied

Amniocentesis

#### ICD-10 code

Z36.0

#### ICD-10 code description

Encounter for antenatal screening for chromosomal anomalies

## Primary outcomes

### 1

#### Description

Pregnant mother anxiety level

#### Timepoint

At the beginning of the study and before and after amniocentesis

#### Method of measurement

Spielberger Anxiety Questionnaire - DOS21  
Questionnaire - Spouse Supportive Behavior Checklist

### 2

#### Description

Pregnant mother stress level

#### Timepoint

At the beginning of the study and before and after amniocentesis

#### Method of measurement

Anxiety and Depression Stress Questionnaire DASS 21

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For the wives of pregnant women in the intervention group, a face-to-face briefing session will be held for 45 to 60 minutes, two to seven days before the amniocentesis. Stress and anxiety of pregnant women and the effect of their presence and support on their husbands in reducing their stress and anxiety level from the time of knowing about the procedure, during the procedure, post-amniocentesis care, how to respond and They will be given time to go to the centers to receive the result. They are also asked to be present with and support their spouses during the amniocentesis. This support will include both physical and psychological parts. In the physical support section, the man takes the pregnant mother's hand with one hand and caresses her with the other hand, facing the mother's face so that she does not see the amniocentesis. In the psychological support section, the man establishes eye contact with the pregnant mother and reminds her of a pleasant memory in order to take his wife's mind away from the sampling area, and the researcher controls and records all these cases through a checklist. In both groups, the amniocentesis will be the same. To do the amniocentesis, the person lies on a test bed and to minimize the risk of infection, the abdomen is disinfected using alcohol. An ultrasound doctor uses a sonography to determine the exact location of the bladder to minimize the risk of harm to the fetus. This may take up to 20 minutes. The doctor then inserts a long, thin needle into the bladder through the abdominal wall and, under ultrasound guidance, closely monitors the process. The doctor removes the required amount of amniotic fluid with a syringe and then removes the needle. Getting fluid may take a few minutes, but it usually takes less than 30 seconds. It is worth mentioning that Spielberg Anxiety Questionnaire, Depression, Anxiety and Stress Questionnaire DASS-21 (Stress Section) by pregnant women in both groups were completed by self-report before and after amniocentesis. The spouse will be present with the pregnant mother while filling out the questionnaire. Also, all these things are done in the presence of the researcher.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam reza hospital

##### Full name of responsible person

Mahin Tafazoli

#### Street address

Ebne\_Sina Street

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#### Email

Tafazolim@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Deputy Research

##### Street address

Ebne\_Sina Street

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Mashhad

##### Province

Razavi Khorasan

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9137913199

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+98 51 3859 1511

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vcresraech@mums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Fatemeh Salehi

##### Position

Master Student of Midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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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