

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The comparison effect of medical and psychological interventions on women's psychiatric disorders after miscarriage

Protocol summary

Summary

The aim of the study is to compare medical and psychological interventions to prevent psychiatric disorders after miscarriage. The 80 eligible women (40 persons with aborted fetus under 12 weeks and 40 persons above 12 weeks) who were 18-40 years old, at least 5 years primary education, elective abortion with medical maternal/fetal causes will be divided into two experimental groups. Women with recurrent abortion, elective abortion with non-medical cause, maternal cause termination that not permitted after pregnancy, severe psychiatric complications, history of infertility will be excluded. 40 persons of experimental group 1 will be received individually medical counseling 2-hours duration by a midwife in a room in the gynecological ward. In this session will be focused on general health and next pregnancy. The experimental group 2 will be referred to a psychologist to consult the patients with grief approach. All the patients will be filled grief questionnaire and Hospital Depression anxiety scale. Also, Patients who suffered from severe psychiatric disorders will be referred to a psychiatric excluded the study. Also, patients with depression, anxiety, or unsolved grief will be invited to psychotherapy in the end of the study.

General information

Acronym

psychological interventions and miscarriage

IRCT registration information

IRCT registration number: **IRCT201312255931N4**

Registration date: **2014-01-03, 1392/10/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name

Mahbobeh Faramarzi

Name of organization / entity

Babol University of medical Sciences

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2016-09-27, 1395/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of medical and psychological interventions on women's psychiatric disorders after miscarriage

Public title

The comparison effect of medical and psychological interventions on women's psychiatric disorders after miscarriage

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: pregnant women under 20 weeks; 18-40 years old; spontaneous abortion or selective abortion; at least 5 years primary education Exclusion criteria: Recurrent abortion; elective abortion with non-medical cause; maternal cause termination with not permitted next pregnancy; severe psychiatric complications; history of infertility

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Babol University of Medical Sciences

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Approval date

2010-12-05, 1389/09/14

Ethics committee reference number

3461

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

psychiatric disorder after abortion

ICD-10 code

o08.8

ICD-10 code description

Other complications following abortion and ectopic and molar pregnancy

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

Depression

Timepoint

immediately, 4 and 16 weeks after consult

Method of measurement

Hospital Depression and anxiety scale

2**Description**

anxiety

Timepoint

immediately, 4 weeks, 16 weeks after intervention

Method of measurement

Hospital Depression Anxiety Scale

Secondary outcomes**1****Description**

Grief

Timepoint

Immediately, 4, 16, after intervention

Method of measurement

Grief Questionnaire

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

Experimental group1: Medical consult for 1 session (2 hours)

Category

Prevention

2**Description**

Experimental group2: psychotherapy for 1 session (2 hours)

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Rohani Hospital

Full name of responsible person

Mahbobeh Faramarzi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name

3461

Grant code / Reference number

3461

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

Yes

Title of funding source

Babol University of Medical Science

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**

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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