

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of psychotherapy and pharmacotherapy on improvement of mental health of depressed women with recurrent spontaneous miscarriage

Protocol summary

Summary

A midwife will be invited to enter the study the women with recurrent abortion who have above 5 years education in Fatemeh Zahra Infertility and Reproductive Health research Center. Invited women fill Beck Depression Inventory and meet a psychologist. women with Beck Depression Inventory 10-30 who established the depression in clinical interview will suggested to enter the study. Severe depressed women excluded the study and refer to a psychiatric. Eligible women will be enter the project with informed consent and fill Problem Infertility Inventory, Spielberger State- Traite Anxiety Inventory (STAI-Y), and Grief questionnaire (GQ). Patients with severe depression excluded the study and refferd to a psychiatric. 60 Eligible women assigned randomly to three equall groups 20 persons; psychotherapy, Pharmacotherapy and control. Psychotherapy group will give 10 session of Cognitive Analytic Group Therapy (1 hours weekly) for 10 weeks. Pharmacotherapy group take Serteralin pill with 100 miligram daily for 10 weeks. Control group did not give any interventions, but their pharmacotherapy or psychotherapy will be started immediatly at the end of study. All patients fiil 4 questionnaires (BDI, FPI, STal-Y, and GQ) at beginning, 10 weeks after the beginning, and 3 month-follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304045931N3**
Registration date: **2013-04-20, 1392/01/31**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-04-20, 1392/01/31

Registrant information

Name

Mahbobeh Faramarzi

Name of organization / entity

Babol University of medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of psychotherapy and pharmacotherapy on improvement of mental health of depressed women with recurrent spontaneous miscarriage

Public title

Comparison of psychotherapy and pharmacotherapy on improvement of mental health of depressed women with recurrent spontaneous miscarriage

Purpose

Treatment
Inclusion/Exclusion criteria
Inclusion criteria: history of three or above spontaneous abortion, education above 5 years, depression mild to moderate. Exclusion criteria: severe depression; attending in psychotherapy sessions and pregnancy

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: **60**
Randomization (investigator's opinion)
Not 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
Street address
Babol- Gang Afroz
City
Babol
Postal code
4715864247
Approval date
2012-12-04, 1391/09/14
Ethics committee reference number
2159

Health conditions studied

1
Description of health condition studied
Recurrent abortion
ICD-10 code
N96
ICD-10 code description
Habitual aborter

Primary outcomes

1
Description
Depression
Timepoint
Beginning of study , after 10 weeks, 3 month-follow up
Method of measurement
Beck Depression Inventory

2
Description
Anxiety
Timepoint
Beginning of study , after 10 weeks, 3 month-follow up
Method of measurement
Spieberger staite-trait Anxiety scale

3
Description
Fertility problem
Timepoint
Beginning of study , after 10 weeks, 3 month-follow up
Method of measurement
Fertility problem Inventory

4
Description
Grief
Timepoint
Beginning of study , after 10 weeks, 3 month-follow up
Method of measurement
Grief Inventory

Secondary outcomes

empty

Intervention groups

1
Description
Psychotherapy group, will give 10 session of Cognitive Analytic Group Therapy (1 hours weekly) for 10 weeks.
Category
Treatment - Other

2
Description
Pharmacotherapy group, take Serteralin pill with 100 miligram daily for 10 weeks.
Category
Treatment - Drugs

3
Description

Control group did not give any interventions

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Infertility and Reproductive Health research Center

Full name of responsible person

Dr.Seddigheh Smaelzadeh

Street address

Babol -Fatemeh Zahra Infertility and Reproductive Health research Center

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical

Full name of responsible person

Dr Mostafazadeh

Street address

Babol- Gang afroz street

City

Babol

Grant name

پژوهشی

Grant code / Reference number

2159

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

Yes

Title of funding source

Babol University of Medical

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

Babol University of Medical Sciences

Full name of responsible person

Mahbobeh Faramarzi

Position

Assistan professor

Other areas of specialty/work

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Web page address

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