

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of the effect of folic acid and 5-methyltetrahydrofolate (5MTHF) on serum folat and homocysteine levels, and abortion rates in women suffering from recurrent abortion

Protocol summary

Summary

Recent data indicates that 5 methyltetrahydrofolate (5MTHF) can reduce serum homocystein level more efficiently than folic acid. On the other hand, folic acid is currently an important part of treatment in idiopathic recurrent abortion. There is no study comparing the effectiveness of these supplements in the treatment of recurrent abortion. The aim of this study is to compare the efficiency of these two agents in the treatment of recurrent abortion. In this study, patients with idiopathic recurrent abortion, referring to Avicenna clinic will be randomly allocated into two groups of those taking either folic acid (5 mg) or 5 MTHF (5mg) from 8 weeks prior to conception until the 20th week of pregnancy. The serum level of folate, homocystein, and ongoing pregnancy will be analysed and compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903034010N1**

Registration date: **2010-06-22, 1389/04/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-22, 1389/04/01

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
National Institute of Nutrition Research

Country

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Recruitment status

Recruitment complete

Funding source

Avicenna Research Institute and National nutrition research institute

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of folic acid and 5-methyltetrahydrofolate (5MTHF) on serum folat and homocysteine levels, and abortion rates in women suffering from recurrent abortion

Public title

Comparison of the effect of folic acid and 5-methyltetrahydrofolate (5MTHF) on serum folat and homocysteine levels, and abortion rates in women suffering from recurrent abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willing to participate in the study and filling out the informed consent form, History of 3 or more idiopathic abortion, the last one should be more

than 6 months ago, no history of intaking folate supplements or high folate containing foods during last 6 months, All previous abortions should be idiopathic without any anatomic, cytologic, hormonal, septic pathologic finding, no special diets Exclusion criteria: elective or induced abortion, molar or ectopic pregnancies, presence of any malignancy, chromosomal abnormality, uterine abnormality, Thyroid, kidney, or liver dysfunction, Glucose intolerance, seizure, Alcohol or drug abuse, Taking any drug affecting homocystein metabolism, not following the study protocol.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Avicenna Ethics Committee

Street address

Avicenna Reserch Institute

City

Tehran

Postal code**Approval date**

2009-09-23, 1388/07/01

Ethics committee reference number

55

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

recurrent abortion

ICD-10 code

O03

ICD-10 code description

spontaneous abortion

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

changes in recurrent abortion successful treatment

Timepoint

20 weeks

Method of measurement

clinical and paraclinical findings

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

serum folate level

Timepoint

8 weeks

Method of measurement

ELISA

2**Description**

Serum Homocystein level

Timepoint

8 weeks

Method of measurement

ELISA

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

5 methyltetrahydrofolate (Intervention, 5 mg, 7 months)

Category

Treatment - Drugs

2**Description**

folic acid (control, 5mg, 7 months)

Category

Treatment - Drugs

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

Avicenna Clinic

Full name of responsible person

Dr. Soheila Arefi

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Avicenna Research Institute and National Institute of Nutrition Research

Full name of responsible person
Azita Hekmatdoost

Street address
Dep Human Nutrition, Shahid Beheshti University of Medical Sciences

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Avicenna Research Institute and National Institute of Nutrition Research

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
Dep Human Nutrition, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Azita Hekmatdoost

Position
Assisatnt Prof

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Person responsible for updating data

Contact

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