Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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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
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Web page address

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