

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of the effect of isotretinoin on the serum level of homocystein with and without folic acid and vit B12 intake

Protocol summary

Summary

Isotretinoin has been used for the treatment of acne. Some previous studies reported elevated homocystein levels after treatment with isotretinoin. Vitamin B12 and folic acid involved in the metabolism of homocystein. We have designed this study with the aim of demonstrating if starting folic acid and Vit B12 replacement therapies with isotretinoin could be useful for preventing hyperhomocysteinemia and possibly related disorders. A total of 56 acne patients over the age of 18 years will be included. They will be allocated randomly in to two groups. One group will receive isotretinoin alone and another group will receive folic acid and Vit B12 in combination with isotretinoin. Serum levels of homocystein, folic acid and Vit B12 will be evaluated and compared in both group before and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081018607N1**

Registration date: **2015-06-29, 1394/04/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-29, 1394/04/08

Registrant information

Name

Maryam Ghiasi

Name of organization / entity

Tehran University of Medical Sciences, Department of Dermatology, Razi Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 5561 8989

Email address

mghiasi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

This project will be supported by Tehran University of Medical Sciences financially.

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of isotretinoin on the serum level of homocystein with and without folic acid and vit B12 intake

Public title

Evaluation of the effect of isotretinoin on the serum level of homocystein with and without folic acid and vit B12 intake

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Acne patients over 18 years of age who have indication of isotretinoin therapy Exclusion criteria: pregnancy; lactation; hyperlipidemia; liver failure; renal failure; diadetes mellitus; hypertension; thyroid dysfunction; psoriasis; Behcet disease; intake of antibiotics of cyclin group; smoking; alcohol use; genetic disorders of aminoacids metabolism; multivitamin or folic acid or vit B12 intake

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

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**

Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Ghods St

City

Tehran

Postal code**Approval date**

2015-06-13, 1394/03/23

Ethics committee reference number

94-01-30-27258-152453

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

Acne

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

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

serum homocysteine level

Timepoint

before and 2 months after treatment

Method of measurement

measurement in laboratory

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

serum vitamin B12 level

Timepoint

before and 2 months after treatment

Method of measurement

measurement in laboratory

2**Description**

serum folic acid level

Timepoint

Before and 2 months after treatment

Method of measurement

Measurement in laboratory

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

Intervention group: Vitamin B12, Amp 1 gram, intramuscular injection, once a month for 2 months

Category

Treatment - Drugs

2**Description**

Intervention group: Folic acid, Tab 1 miligram, oral, once a day for 2 months

Category

Treatment - Drugs

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

Razi Hospital

Full name of responsible person

Maryam Ghiasi

Street address

Razi Hospital, Vahdat Eslami Sq, Tehran, Iran

City

Tehran

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masud Yunesian

Street address

Ghods St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

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**

Tehran University of Medical Sciences, Department of Dermatology

Full name of responsible person

Maryam Ghiasi

Position

Associate Professor

Other areas of specialty/work**Street address**

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Tehran University of Medical Sciences, Department of

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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*