

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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, Departement 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**Person responsible for updating data****Contact****Name of organization / entity**

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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