Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

the effect of systemic isotretinoin on the nasal and oropharyngeal microbial flora in patients with acne vulgaris

Protocol summary

Summary
objective: In this study the effects of systemic isotretinoin will be evaluated on normal flora of the nose and throat. design: This is a clinical trial study setting and conduct: Before and three months after starting treatment, three nasal and oropharynx samples will be taken wit a sterile swab. Normal flora and potential pathogens bacteria differences before and 3 months after of treatment will be examined in a patient with acne vulgaris referring to BoAli Sina Hospital, Sari. Participants including major eligibility: people over 13 years of age with moderate to severe acne. intervention: Isotretinoin treatment will be done with a daily dose of 0.5 mg/kg for 3 months. main outcomes: normal and pathogen microbial flora of nose and throat

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2016120427636N4**
Registration date: **2017-04-10, 1396/01/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2017-04-10, 1396/01/21

Registrant information

Name
Ghasem Rahmatpour Rokni
Name of organization / entity
Mazandaran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source
Deputy of Science and Technology, Mazandaran University of Medical Sciences

Expected recruitment start date
2016-06-21, 1395/04/01
Expected recruitment end date
2016-12-21, 1395/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
the effect of systemic isotretinoin on the nasal and oropharyngeal microbial flora in patients with acne vulgaris

Public title
the effect of oral isotretinoin on the nasal and oral bacteria in patients with acne
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: 1. Patients with moderate to severe acne candidates for systemic isotretinoin therapy.;consent to participate in the study Exclusion criteria: Patients who are pregnant or lactating women;topical or systemic anti-acne drugs or antibiotics were used a month prior to or in conjunction with study.; Patients have been affected with infectious and respiratory diseases a month before o during the study.; Patients with chronic liver disease or peptic ulcer 5- consumers of drugs that cause acne include: vitamin B12, topical steroids or systemic anti-TB drugs, lithium,

azathioprine, carbamazepine and phenytoin;patients with Hematologic disorders (according hematologic side effects of treatment)

Age
From **13 years** old to **50 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee, Mazandaran University of Medical Sciences

Street address
Moallem square,Sari

City
Sari

Postal code

Approval date
2016-02-01, 1394/11/12

Ethics committee reference number
IR.MAZUMS.REC.94-1460

Health conditions studied

1

Description of health condition studied
acne vulgaris

ICD-10 code
L70.0

ICD-10 code description
Acne vulgaris

Primary outcomes

1

Description
nose and throat microbial flora

Timepoint
before treatment intervention & 3 months after treatment intervention

Method of measurement
Laboratory

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Intervention group: systemic isotertinoein(oral),0.5 mg/kg,daily,for 3 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bu-Ali Sina hospital

Full name of responsible person
Dr. Ghasem Rahmatpour Rokni

Street address
Bu-Ali Sina hospital, Pasdaran blvd,Sari.

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Mazandaran University of Medical Sciences

Full name of responsible person
Ahmad Ali Enayati

Street address
NO.2 Building of Mazandaran University of Medical Sciences,Moallem Square
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Mazandaran 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

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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