

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

A comparison survey of GATA-3, RORyt and FOXP3 genes expression levels in peripheral blood cells of rhinitis patients, before and after treatment with fexofenadine and budesonide.

Protocol summary

Summary

In this study people who have clinical sign and symptoms of rhinitis (nasal congestion, rhinorrhea, sneezing, itchy nose, headache, earache, itchy throat, snoring or postnasal drip) after diagnosis by specialist of allergy will enter the study. Next we make an interview with patients and we explain the situations of the study for the patients. If patients Satisfy and desire the study, they will enter the study. From each patient, before treatment and after one month treatment, 5 ml blood will be taken. Treatment will be done in one month with anti-histamine (Fexofenadine) and Intranasal corticosteroid (budesonide). Blood samples will transfer to CBC vials containing anti coagulant (EDTA) and quickly will transfer to the lab. Next, using RNA extraction kit, RNA will be extracted from peripheral blood cells of taken bloods. Then, using Reverse transcriptase enzyme, extracted RNA will be transcribed to cDNA and will be store in -20 °C until real time test. Then the level of expression of transcription factors, GATA-3, RORyt and Foxp3 in blood samples will be measured, in relative measurement, by use of Real-time PCR and sybergreen method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042433622N1**
Registration date: **2017-05-16, 1396/02/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-16, 1396/02/26

Registrant information

Name

Ali Gorgin Karaji

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research and Technology,
Kermanshah University of Medical Sciences

Expected recruitment start date

2017-05-13, 1396/02/23

Expected recruitment end date

2017-07-14, 1396/04/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison survey of GATA-3, RORyt and FOXP3 genes expression levels in peripheral blood cells of rhinitis patients, before and after treatment with fexofenadine and budesonide.

Public title

Effect of Fexofenadine and budesonide on the level of transcription factors: GATA-3, RORyt and FOXP3 in allergic rhinitis patients

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: the age of man and women between 18 to 60, Signature the testimonial by the patients before entrance to the study, having rhinitis symptoms which is confirmed by specialist physician, lack of abnormality in nasal anatomy, not being suffered from: asthma, infectious disease, underlying diseases such as diabetes and chronic inflammatory diseases. In addition, pregnant women, people above 65 and those people who suffer from rhinitis because of Senility will not enter the study. Exclusion criteria: People suffering from infectious diseases or common cold and patients taking drugs other than drugs that must consume according to the research plan, during Performance of the project, will be excluded. In addition, patients who have a fungal, viral or bacterial disease during the study and patients who do not follow the recommended instructions will be excluded.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

No. 2 bulding of KUMS, Beheshti Bolvard, Kermanshah

City

Kermanshah

Postal code

6714673159

Approval date

2017-02-22, 1395/12/04

Ethics committee reference number

KUMS.REC.1395.716

Health conditions studied

1

Description of health condition studied

Rhinitis

ICD-10 code

J30-J31

ICD-10 code description

Vasomotor and allergic rhinitis and Chronic rhinitis, nasopharyngitis and pharyngitis

Primary outcomes

1

Description

GATA3, FOXP3 and RORgt

Timepoint

Befor treatment and After one month treatment

Method of measurement

Relative expression of GATA3, FOXP3 and RORgt measured by Real-time PCR

Secondary outcomes

empty

Intervention groups

1

Description

Fexofenadine: One tablet per day Budesonide: One Puff per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Kermanshahi Hospital

Full name of responsible person

Dr. Seyed Hamid Reza Mortazavi

Street address

Dr Kermanshahi Hospital, Helal Ahmar Crossroad, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

Full name of responsible person

Behrooz Hamzeh

Street address

NO. 2 Bulding of Vice Chancellor for Research and
Technology, Shahid Beheshti Blv. Kermanshah, Iran

City

Kermanshah

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 and Technology

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

School of Medicine, Kermanshah University of Medical
Sciences

Full name of responsible person

Ali Gorgin Karaji

Position

University Lecturer

Other areas of specialty/work

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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