

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Effects of Ketotifen Fumarate Drop and Ketotifen Pill on Symptom Severity, Quality of Life and Nasal Smear Eosinophil Percent in Allergic Rhinitis Patients: a Randomized Clinical Trial

Protocol summary

Summary

This study is designed to assess the effects of ketotifen fumarate drop and compares it with Ketotifen pill within 4-weeks after intervention. One hundred and fifty mild allergic rhinitis patients, referred to Baqiyatallah University of Medical Sciences Allergy Clinic will be enrolled to the study. Allergic rhinitis approves by clinical examination, history, and diagnostic tests. Patients consuming antihistamines and corticosteroids, refractory to antihistamines and leukotriene receptor antagonists, patients with asthma, acute and chronic rhino-sinusitis, polyposis, consuming tricyclic antidepressants and allergy to ketotifen will be excluded. Patients will be randomized to ketotifen fumarate 0.025% drop (one drop in each side of nose every 12 hours) with placebo pills (every 12 hours) and Placebo drop (one drop every 12 hours), with ketotifen pills (1 mg every 12 hours) groups. Patients will be evaluated by endoscopy, symptoms (sneezing, runny nose, itching, and nasal obstruction) severity score (0-10 VAS score), quality of life, and eosinophil percent for nasal smears, within 4-weeks treatment in 3 visits. Collected data will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051617413N3**
Registration date: **2014-08-21, 1393/05/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-21, 1393/05/30

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 4354

Email address

hrkarimisari@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences, Deputy of Research

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-08-16, 1393/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Ketotifen Fumarate Drop and Ketotifen Pill on Symptom Severity, Quality of Life and Nasal Smear Eosinophil Percent in Allergic Rhinitis Patients: a Randomized Clinical Trial

Public title

Comparison Therapeutic Effects of Ketotifen Fumarate Drop and Ketotifen Pill in Patients with Allergic Rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Mild allergic rhinitis patients referred to Baqiyatallah University of Medical Sciences Allergy Clinic without any age and gender limitations. Exclusion criteria: Patients consuming antihistamines and corticosteroids; refractory to antihistamines and leukotriene receptor antagonists; patients with asthma; acute and chronic rhino-sinusitis; polyposis; consuming tricyclic antidepressants; allergy to ketotifen

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Sciences Ethics Committee

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Approval date

2013-07-24, 1392/05/02

Ethics committee reference number

31

Health conditions studied

1

Description of health condition studied

allergic rhinitis

ICD-10 code

J30

ICD-10 code description

Vasomotor and allergic rhinitis

Primary outcomes

1

Description

Rhinorrhea severity

Timepoint

Before treatment, two weeks and four weeks after treatment

Method of measurement

visual analogue score (0-10)

2

Description

Itchy nose severity

Timepoint

Before treatment, two weeks and four weeks after treatment

Method of measurement

visual analogue score (0-10)

3

Description

Quality of life

Timepoint

Before treatment, two weeks and four weeks after treatment

Method of measurement

Rhino-conjunctivitis quality of life questionnaire (RQLQ)

4

Description

Eosinophil percent for nasal smears

Timepoint

Before treatment, two weeks and four weeks after treatment

Method of measurement

Nasal smears laboratory test

5

Description

Nasal obstruction severity

Timepoint

Before treatment, two weeks and four weeks after treatment

Method of measurement

visual analogue score (0-10)

Secondary outcomes

empty

Intervention groups

1

Description

Ketotifen fumarate 0.025% drop, one drop in each side of nose every 12 hours, and placebo pills every 12 hours, for four weeks

Category

Treatment - Drugs

2

Description

Placebo (distilled water) drop, one drop in each side of nose every 12 hours, and ketotifen pills, 1 mg every 12 hours, for four weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah University of Medical Sciences Policlinic

Full name of responsible person

Hamidreza Karimi Sari

Street address

Baqiyatallah Polyclinic, Nosrati alley, Sheikh Bahaei St. Mollasadra St. Vanak Sq. Tehran, I.R.Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences, Deputy of Research

Full name of responsible person

Esmail Arefzadeh

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Baqiyatallah University of Medical Sciences, Deputy of 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

Students' Research Committee (SRC), Baqiyatallah University of Medical Sciences, Tehran, IR Iran

Full name of responsible person

Hamidreza Karimi Sari

Position

General Practitioner

Other areas of specialty/work

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Phone

+98 21 8126 4354

Fax

+98 21 8126 4354

Email

dr.karimih@yahoo.com

Web page address

<http://bmsusrc.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of ENT, Baqiyatallah University of Medical Sciences, Tehran, Iran

Full name of responsible person

Ashghar Akhavan

Position

Associate Professor

Other areas of specialty/work

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Phone

+98 21 8126 4354

Fax

Email

dr_akhavan_ent@yahoo.com

Web page address

http://a_akhavan.cv.research.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity

Students' Research Committee (SRC), Baqiyatallah
University of Medical Sciences (BMSU), Tehran, Iran

Full name of responsible person

Hamidreza Karimi Sari

Position

General Practitioner

Other areas of specialty/work

Street address

Baqiyatallah University of Medical Sciences, Nosrati
alley, Sheikh Bahaei Street, Mollasadra Street, Vanak
Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Phone

+98 21 8126 4354

Fax

+98 21 8126 4354

Email

dr.karimih@yahoo.com

Web page address

<http://bmsusrc.ir/>

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