Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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

1

Sponsor
Name of organization / entity
Baqiyatallah University of Medical Sciences, Deputy of Research
Full name of responsible person
Esmaeil Arefzadeh
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Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.
City
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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
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Person responsible for scientific 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