

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Extract of *Urtica dioica* on perennial Allergic Rhinitis

Protocol summary

Summary

Purpose: Effect of Extract of *Urtica dioica* on perennial Allergic Rhinitis, Design and criteria: This study is prospective, Randomized, double blinded and clinical trial. (Drug distributors and patients are blind about the type of drug). 20 Patients with symptoms of allergic rhinitis, referred to Immunology and ENT clinic were chosen and divided randomly into two group. The first group were treated with *urtica dioica* (150 mg qid for one month) and the second group were treated with placebo for one month. Before and after treatment IL 5, IL4 and INF-gamma are compared. Inclusion criteria: Clinical and laboratory diagnosis perennial allergic rhinitis; Patients' willingness to participate in treatment and plan Exclusion criteria: The risk of other causes of rhinitis; Systemic diseases such as polycythemia; Use of other drugs with anti-inflammatory properties; Use of any herbal remedy; Intolerance of side effects *urtica dioica*; Drug use weak immune system; Use of antidiabetic drugs; Use of hypertensive drugs; Pregnancy & Breastfeeding; Age less than 15 years and more than 45 years. Primary outcome: Diagnostic symptoms of Allergic rhinitis. Secondary outcome: Blood level of IgE, Blood level of IL5, Blood level of IL4, Blood level of INF Gamma, Nasal eosinophil count. Intervention group: The patients were treated with *urtica dioica* (150 mg qid for one month). Control group: The patients were treated with placebo for one month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102715177N1**

Registration date: **2013-11-19, 1392/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-19, 1392/08/28

Registrant information

Name

Mehdi Bakhshae

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 4082

Email address

bakhshaeem@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Science

Expected recruitment start date

2013-05-10, 1392/02/20

Expected recruitment end date

2013-10-02, 1392/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Extract of *Urtica dioica* on perennial Allergic Rhinitis

Public title

Effect of Extract of *Urtica dioica* on perennial Allergic Rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Clinical and laboratory diagnosis perennial allergic rhinitis; Patients' willingness to participate in treatment and plan Exclusion criteria: The risk of other causes of rhinitis; Systemic diseases such as

polycythemia; Use of other drugs with anti-inflammatory properties; Use of any herbal remedy; Intolerance of side effects urtica dioica; Drug use weak immune system; Use of antidiabetic drugs; Use of hypertensive drugs; Pregnancy & Breastfeeding; Age less than 15 years and more than 45 years.

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

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**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Ghoreishi apartment, Daneshgah st, Mashhad

City

Mashhad

Postal code**Approval date**

2013-05-04, 1392/02/14

Ethics committee reference number

910557

Health conditions studied**1****Description of health condition studied**

Allergic Rhinitis

ICD-10 code

J30.3

ICD-10 code description

Other allergic rhinitis

Primary outcomes**1****Description**

Symptoms of Allergic rhinitis

Timepoint

Before and after treatment

Method of measurement

SNOT - 22

Secondary outcomes**1****Description**

Blood level of IgE

Timepoint

Before and after treatment

Method of measurement

ELISA

2**Description**

Blood level of IL5

Timepoint

Before and after treatment

Method of measurement

ELISA

3**Description**

Blood level of IL4

Timepoint

Before and after treatment

Method of measurement

ELISA

4**Description**

Blood level of INF Gamma

Timepoint

Before and after treatment

Method of measurement

ELISA

5**Description**

Nasal eosinophil count

Timepoint

Before and after treatment

Method of measurement

Eosinophil count

Intervention groups

1

Description

Intervention group: The patients were treated with urtica dioica (150 mg qid for one month

Category

Treatment - Drugs

2

Description

Control group: The patients were treated with placebo for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Street address

City

Mashhad

2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Street address

City

Mashhad

3

Recruitment center

Name of recruitment center

Faculty of Pharmacy

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Science

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreishi building, Daneshgah street, Mashhad

City

Mashhad

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, Mashhad University of Medical Science

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

Mashhad university of Medical Science

Full name of responsible person

Mehdi Bakhshae

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad university of Medical Science

Full name of responsible person

Mehdi Bakhshae

Position**Other areas of specialty/work****Street address****City****Postal code****Phone**

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Fax**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