# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 Bakhshaee

**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**
Befor 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 Bakhshaee
**Position**
Associate Professor
**Other areas of specialty/work**
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Bakhshaeem@mums.ac.ir
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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**Other areas of specialty/work**
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**Fax**
**Email**
**Web page address**

## 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*