

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of anti lophomonas parasite treatment on patients chronic cough well-being

#### Protocol summary

##### Study aim

Studying the effect of anti lophomonas parasite treatment on patients chronic cough well-being

##### Design

It is a Randomized, singles center, controlled clinical trial with a parallel group design and double blinded outcomes assessment. Randomization was done by Randomizer website ( www.randomizer.org).

##### Settings and conduct

This study will be done in asthma specialist clinic. After explaining the study for the patients, informed consent will be signed by them if they accept to enter the study.cough and its grading ,sputum and its color , dyspnea and its grading ,body temperature ,post nasal drip(PND),Lophomonas being and grading of inflammatory cell in sputum Smear and bronchoalveolarlavage(BAL) will be done and recorded before and after the treatment.these smears that will be colored by trichrome stain and will be studied by optical microscope.

##### Participants/Inclusion and exclusion criteria

patients suffering from more than one months cough who could not be controlled by past medical treatment,patients with normal physical examination , patients with normal chest x ray

##### Intervention groups

This study consists of Two groups of 30 patients. Patients in the first group takes Tinidazole 500 mg, and the second group take Placebo each 12 hours. Patients in each group will take the drugs for 2 weeks.

##### Main outcome variables

Tinidazole treatment cough grading sputum color of sputum Airway hyperresponsiveness (AHR) Dyspnea dyspnea grading body temperature post nasal drip (PND) Lophomonas in sputum smear or Bronchoalveolar lavage (BAL) Grading of Inflammatory cells in sputum smear or Bronchoalveolar lavage (BAL)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20091111002695N10**

Registration date: **2020-12-07, 1399/09/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-07, 1399/09/17**

Update count: **0**

##### Registration date

2020-12-07, 1399/09/17

##### Registrant information

##### Name

Majid Mirsadraee

##### Name of organization / entity

Islamic Azad University- Mashhad branch

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3841 6694

##### Email address

majidmirsadraee@mshdiau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-05, 1399/09/15

##### Expected recruitment end date

2021-03-05, 1399/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of anti lothomonas parasite treatment on patients chronic cough well-being

**Public title**

Effect of anti lothomonas parasite treatment on patients chronic cough well-being

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients suffering from more than one months cough who could not be controlled by past medical treatments patients with normal physical examination patients with normal chest-x-ray

**Exclusion criteria:**

drug allergy proven asthma Tuberculosis(TB), gastroesophageal reflux(GERD) , ear wax, Chronic Obstructive Pulmonary disease(COPD), Carcinoma,hemoptesis Angiotensin converting enzyme inhibitors(ACEI) users

**Age**

From **15 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization was done by Randomizer website ( [www.randomizer.org](http://www.randomizer.org)).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All the drugs will be prepared with united shape, color and packages. the only difference is the code on the package. The drugs will be given to our colleague who is present in the clinic everyday and is blinded to the types of the drugs and groups of treatment. Each time the patients refer to our clinic they will receive the same drug based on their randomized code.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University- Mashhad branch

**Street address**

Shahin Far Building, sarab alley, Azadi street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9178673799

**Approval date**

2019-06-30, 1398/04/09

**Ethics committee reference number**

IR.IAU.MSHD.REC.1398.049

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

chronic cough

**ICD-10 code**

R05

**ICD-10 code description**

Cough

**2****Description of health condition studied**

Lophomonas Blattarum

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Lophomonas Blattarum being in smear or Bronchoalveolarlavage

**Timepoint**

Before intervention and 14 days after intervention

**Method of measurement**

Trichrome staining

**2****Description**

Chronic cough grading

**Timepoint**

Before intervention and 14 days after intervention

**Method of measurement**

Global Initiative for Asthma (GINA) guideline

**Secondary outcomes**

## 1

### **Description**

dyspnea

### **Timepoint**

Before intervention and 14days after intervention

### **Method of measurement**

physical examination

## 2

### **Description**

sputum inflammatory cells

### **Timepoint**

Before intervention and 14days after intervention

### **Method of measurement**

sputum cytology

## 3

### **Description**

dyspnea garding

### **Timepoint**

Before intervention and 14 days after intervention

### **Method of measurement**

GINA(global strategy for asthma)

## 4

### **Description**

Body temperature

### **Timepoint**

Before intervention and 14days after intervention

### **Method of measurement**

Thermometer

## **Intervention groups**

## 1

### **Description**

Intervention group: Tinidazole 500mg in form of tablet, one each 12 hours, for 14 days. The Active Pharmaceutical Ingredient is provided by Pars daru Pharmaceutical company

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: Placebo in form of tablet B1 300 mg from Jalinus Pharmaceutical company, one each 12 hours, for 14 days.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

**Name of recruitment center**

Asthma specialist clinic

### **Full name of responsible person**

Majid Mirsadraee

### **Street address**

No 80, 15th Kosar, Kosar Ave., Vakilabad Blv.

### **City**

Mashhad

### **Province**

Razavi Khorasan

### **Postal code**

9187147578

### **Phone**

+98 51 3870 4347

### **Email**

majidmirsadraee@mshdiau.ac.ir

### **Web page address**

<http://drmirsadraee.ir>

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Islamic Azad University

#### **Full name of responsible person**

Esmail kheirkhah

#### **Street address**

Islamic Azad University of Mashhad, Ostad yousefi St., Emamiyeh Blv, Ghasemabad

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9187147578

#### **Phone**

+98 51 3663 7842

#### **Email**

research@mshdiau.ac.ir

#### **Web page address**

<http://vcr.mshdiau.ac.ir/>

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Islamic Azad University

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Majid Mirsadraee

**Position**

Full professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No 80, 15th Kosar, Kosar Ave., Vakilabad Blv.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9187147578

**Phone**

+98 51 3870 4347

**Email**

majidmirsadraee@mshdiau.ac.ir

**Web page address**

<http://drmirsadraee.ir/>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Majid Mirsadraee

**Position**

Full professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No 80, 15th Kosar, Kosar Ave., Vakilabad Blv

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9187147578

**Phone**

+98 51 3870 4347

**Email**

majidmirsadraee@mshdiau.ac.ir

**Web page address**

<http://drmirsadraee.ir/>

## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Majid Mirsadraee|j|

**Position**

Full Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No 80, 15th Kosar, Kosar Ave., Vakilabad Blv.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9187147578

**Phone**

+98 51 3870 4347

**Email**

majidmirsadraee@mshdiau.ac.ir

**Web page address**

[http://drmirsadraee.ir](http://drmirsadraee.ir/)

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

treat with Tinidazole( before and after treatment), cough garding( before and after treatment),sputum and its color ( before and after treatment), dyspnea and its grading( before and after treatment), temperature ( before and after treatment), Lophomonas existing in smear or BAL( before and after treatment), Inf cells grading in sputum and BAL( before and after treatment), Sex and age

**When the data will become available and for how long**

One Month after publishing the results.

**To whom data/document is available**

There will be no limitation for accessing the data.

**Under which criteria data/document could be used**

There will be no limitation for accessing the data. If someone need to use the data, he/she might ask the corresponding author for permission.

**From where data/document is obtainable**

Contact the corresponding author.

**What processes are involved for a request to access data/document**

After contacting the corresponding author via phone or

Email, the data will be provided.

**Comments**