

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Ivermectin effect in treatment of patients with human fascioliasis

#### Protocol summary

##### Summary

Ivermectin effect in treatment of patients with fascioliasis, Ivermectin is a semisynthetic, anthelmintic agent for oral administration. Ivermectin is derived from the avermectins (a class of highly active broad-spectrum). Ivermectin is a mixture containing at least 90% 5-O-demethyl-22,23-dihydroivermectin and less than 10% 5-O-demethyl-25-de(1-methylpropyl)-22,23-dihydro-25-(1-methylethyl)ivermectin, generally referred to as 22,23-dihydroivermectin. Its peak plasma concentration is 46 nanograms per mL after a single 12-mg dose. Ivermectin is metabolized by the liver and is excreted in the feces over an estimated period of 12 days, with less than 1% of the dose excreted in the urine. Ivermectin binds selectively and with high affinity to glutamate-gated chloride ion channels in invertebrate muscle and nerve cells of the microfilaria. This binding causes an increase in the permeability of the cell membrane to chloride ions and results in hyperpolarization of the cell, leading to paralysis and death of the parasite. It's an experimental, open label and pilot study. It's studied on patients with Fasciola in the first six months of 1390 until the number reaches to 40 patients. In this period all people over 18 years old with Fasciola symptoms include: fever, sweating, weakness, fatigue, cough, pain in RUQ, epigastric pain, nausea, vomiting, skin rashes, skin lesions, muscle pain, Jaundice, weight loss associated with positive laboratory tests include: ELISA (+) and hypereosinophilia in CBC diff and the lack of exclusion criteria included: pregnancy, lactation, hypersensitivity to the drug come to Anzali Health Care and they are referred for treatment to Gastrointestinal and Liver Diseases Research Center (GLDRC) in Guilan province Rasht city. In GLDRC after obtaining consent from a patient, questionnaire included: personal data, previous history of Fasciola treatment, symptoms before treatment, tests (S / E, ELISA, ALK-P, ALT, AST, CBC diff) before treatment and prior to ultrasound fill then it's given appropriate dose Ivermectin 200 microgram per kg, ie 3 mg two tablets

morning and night in one day to the patient. The patients follow by phone 24 and 48 and 72 hours after treatment. They visit 15 days, 1 month and 3 months after treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201105291155N13**

Registration date: **2011-06-18, 1390/03/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-06-18, 1390/03/28

##### Registrant information

##### Name

Farahnaz Joukar

##### Name of organization / entity

Guilan University of Medical Sciences,  
Gastrointestinal and liver disease Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1553 5116

##### Email address

info@glsrc.org

##### Recruitment status

##### Recruitment complete

##### Funding source

Vince chancellor for reaserch Guilan univercity of medical sciences

##### Expected recruitment start date

2011-06-22, 1390/04/01

##### Expected recruitment end date

2011-12-22, 1390/10/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Ivermectin effect in treatment of patients with human fascioliasis

**Public title**  
Ivermectin effect in treatment of patients with human fascioliasis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: persons are over 18 years old with human fascioliasis Exclusion criteria: pregnancy;lactation;hypersensitivity to the drug

**Age**  
From **18 years** old to **75 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**Placebo**

Not used  
**Assignment**

Single  
**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

**Name of ethics committee**  
Guilan University of Medical Sciences. Ethics Committee Gastrointestinal and Liver Diseases Research

**Street address**  
Sardar Jangal Ave, Gastrointestinal and Liver Diseases Research Center, Razi Hospital, Rasht, Iran

**City**  
Rasht

**Postal code**  
955655-41488

**Approval date**

2011-05-26, 1390/03/05  
**Ethics committee reference number**  
161/ش

## Health conditions studied

1

### Description of health condition studied

Fasciola

### ICD-10 code

B66.3

### ICD-10 code description

Infection due to Fasciola

## Primary outcomes

1

### Description

Ivermectin effect in treatment of patients with Fascioliasis

### Timepoint

1 month and 3 months after treatment

### Method of measurement

negative ELISA- negative S/E-absence of hypereosinophilia-recovery of patients signs

## Secondary outcomes

empty

## Intervention groups

1

### Description

Ivermectin effect in treatment of patients with Fascioliasis It's given appropriate dose Ivermectin 200 microgram per kg, ie 3 mg two tablets morning and night in one day to the patient.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Gastrointestinal and liver disease research center

#### Full name of responsible person

farahnaz joukar

#### Street address

Sardar jangle Ave-Razi hospital-Gastrointestinal and liver disease research center

#### City

Rasht

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vince chancellor for reaserch Guilan univercity of medical sciences

**Full name of responsible person**

Dr Rasool Tabari KHomeirani

**Street address**

Sadati st, Samjoo st, Rasht,Guilan

**City**

Rasht

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vince chancellor for reaserch Guilan univercity of medical sciences

**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**

gastrointestinal and liver disease research center (GLDRC)

**Full name of responsible person**

Farahnaz Joukar

**Position**

assistant of gastrointestinal and liver disease research center (GLDRC)

**Other areas of specialty/work****Street address**

gastrointestinal and liver disease research center (GLDRC) - Razi hospital - Sardar Jangal Ave.

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**Web page address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

gastrointestinal and liver disease research center (GLDRC)

**Full name of responsible person**

Dr.Fariboraz Mansou-Ghanaei

**Position**

Head / Full Professor of Internal Medicine & Gastroenterology

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Gastrointestinal and liver disease research center

**Full name of responsible person**

Dr. Maryam Bakhshandeh

**Position**

Researcher

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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*