Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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-dihydroavermectin and less than 10% 5-O-demethyl-25-de(1-methylpropyl)- 22,23-dihydro-25-(1-methylethyl)avermectin , generally referred to as 22,23-dihydroavermectin . 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 lable 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 CBCdiff and the lack of exclusion criteria included: pregnancy, lactation, hypersensitivity to the drug come to Anzali Health Care and they are reffered 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

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Farahnaz Joukar

Name of organization / entity

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

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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;hypersensitivy 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

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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

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

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Sponsors / Funding sources

1

Sponsor
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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
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

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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