

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Phase I/II, Randomized, Double-Blind Intervention Trial for Evaluating the Safety and Efficacy of Imatinib in Subjects with Advance fibrosis

Protocol summary

Study aim

A Phase I/II, Randomized, Single-Blind Intervention Trial for Evaluating the Safety and Efficacy of Imatinib in Subjects with Advance fibrosis (grade 3, 4)

Design

A phase I/II clinical trial with control group, double blind labeled and randomized double armed. With a parallel group design of 60 patients and permuted block randomization with block size 4.

Settings and conduct

Registration of patients depending on inclusion and exclusion criteria for two parallel groups. All patients and medical doctors are blind about receiving placebo or imatinib.

Participants/Inclusion and exclusion criteria

Males or females between 18-75 years old with a clinically confirmed diagnosis of Fibrosis with grade 3-4 by Metavir score. BMI >25 Negative alcohol screen. Able to understand and willing to voluntarily sign an informed consent form (ICF) and Health Insurance Portability and Accountability Act (HIPAA) authorization; Known cardiovascular disease. Requiring any of the following medications during the duration of the study: History of cirrhosis, hepatic encephalopathy or variceal bleeding. History of hepatocellular carcinoma (HCC). History of malignancy and serious infections. Females who are pregnant or breastfeeding.

Intervention groups

30 patients will be given standard medication and imatinib. 30 patients will be given standard medication and placebo.

Main outcome variables

Assessment of liver fibrosis score by the FibroScan system; Detecting serological changes of alanine aminotransferase, aspartate aminotransferase serum levels, blood sugar and fasting insulin test, albumin, Bilirubin, complete blood count, Alkaline phosphatase, international normalized ratio, prothrombin time. Detecting changes of the serum inflammation markers:

Tumor necrosis factor (TNF)-alpha, Interleukin-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200809048342N1**

Registration date: **2020-08-25, 1399/06/04**

Registration timing: **prospective**

Last update: **2020-08-25, 1399/06/04**

Update count: **0**

Registration date

2020-08-25, 1399/06/04

Registrant information

Name

Kaveh Baghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Phase I/II, Randomized, Double-Blind Intervention Trial for Evaluating the Safety and Efficacy of Imatinib in Subjects with Advance fibrosis

Public title

Effect of imatinib in advance liver fibrosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Males or females between 18-75 years old with a clinically confirmed diagnosis of Fibrosis with grade 3-4 by Metavir score. BMI >25 Negative alcohol screen. Able to understand and willing to voluntarily sign an informed consent form (ICF) and Health Insurance Portability and Accountability Act (HIPAA) authorization.

Exclusion criteria:

Known cardiovascular disease. Requiring any of the following medications during the duration of the study: History of cirrhosis based on imaging or clinical criteria and/or hepatic decompensation including ascites, hepatic encephalopathy or variceal bleeding. History of hepatocellular carcinoma (HCC) History of malignancy within the past 5 years or ongoing malignancy other than basal cell carcinoma, or resected noninvasive cutaneous squamous carcinoma at the time of Screening visit Active, serious infections that requires parenteral antibiotic or antifungal therapy within 30 days prior to Screening visit. Females who are pregnant or breastfeeding. Current or anticipated treatment with radiation therapy, cytotoxic chemotherapeutic agents and immunomodulating agents (such as systemic corticosteroids, interleukins, interferons). Use of any experimental medications within the last 6 months of Screening Visit. Any other clinically significant disorders or prior therapy that, in the opinion of the investigator, would make the subject unsuitable for the study or unable to comply with the dosing and protocol requirements. Familial dyslipidemia Weight loss of >5% within 6 months prior to Screening, based on subject's reporting Currently or participated in a weight loss program within the last 6 months Any history of bariatric surgery Diabetes mellitus Type I Daily alcohol intake >20 ml (2 units)/day for women and 30 ml (3 units)/day for men (on average), as per Alcohol Use Disorders Identification Test (AUDIT) questionnaire at Screening and plan to consume the same alcohol amount referenced above during the trial Use of any immunosuppressive medication, anti-inflammatory monoclonal antibody treatment, or chronic systemic corticosteroids >10 mg prednisone-equivalent concurrently or within 1 year prior to Screening Uncontrolled or clinically unstable thyroid disease, in the judgment of the Principal Investigator. History or presence of hepatitis B or C or human immunodeficiency virus (HIV) Uncontrolled arterial hypertension Any severe, acute, or chronic medical or psychiatric condition that may increase the risk associated with study participation or study drug administration, may interfere with the informed consent process and/or with

compliance with the requirements of the study, or may interfere with the interpretation of study results and, in the investigator's opinion, would make the subject inappropriate for entry into this study. Subjects who have previously received imatinib or who have history of hypersensitivity, allergy, intolerance or contraindication to imatinib.

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with block size 4. Participants were assigned to two groups of Imatinib drug and placebo using block randomization method (quadruple blocks with equal volume). This ensures balance in the number of groups. In this study, due to the existence of two treatment groups, for 4 blocks, there will be six different manners as follows: (Control group=C and Treatment group=T) 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC Randomized selection will be carried out each time by Random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

- All participants (patients) will be inform about research project. - All patients and medical doctors are blind about receiving placebo or imatinib. - Academic researchers are aware about receiving treatments for all patients. - The blind approach would be accomplished by giving the doctor unknown sealed drug or placebo, hence, both the physician and the patients are blind in terms of medication and placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti university of medical science

Street address

Research Institute for Gastroenterology and Liver Diseases, taleghani hospital, Arabi st., Velenjak ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985714711

Approval date

2020-07-18, 1399/04/28

Ethics committee reference number

IR.SBMU.RIGLD.REC.1399.032

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

liver fibrosis grade3-4

ICD-10 code

K74

ICD-10 code description

Fibrosis and cirrhosis of liver

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

Assessment of liver fibrosis score by the FibroScan system;

Timepoint

Before starting the administration, and at the end of the trial

Method of measurement

FibroScan system

2**Description**

Detecting serological changes of: alanine aminotransferase serum levels aspartate aminotransferase serum levels Alkaline phosphatase albumin Bilirubin

Timepoint

Before starting the administration, after 3 months and at the end of the trial.

Method of measurement

Serology testing

3**Description**

Blood sugar and fasting insulin test

Timepoint

Before starting the administration, after 3 months and at the end of the trial.

Method of measurement

Blood test

4**Description**

Complete blood count

Timepoint

Before starting the administration, after 3 months and at the end of the trial.

Method of measurement

Blood test

5**Description**

International normalized ratio and prothrombin time

Timepoint

Before starting the administration, after 3 months and at the end of the trial.

Method of measurement

Blood test

6**Description**

Detecting changes of the serum inflammation markers: Tumor necrosis factor (TNF)-alpha, Interleukin-6

Timepoint

Before starting the administration and at the end of the trial.

Method of measurement

Serology testing

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: patients will be given imatinib orally daily for 24 weeks. The dose will be 200mg/day. Sold under the brand names Gleevec. Its chemical formula is C29H31N7O. The importer company of the drug used in this clinical trial is Sobhan Oncology Pharmaceutical Company and its manufacturer is CIPLA Company in India.

Category

Treatment - Drugs

2**Description**

Control group: patients will be given placebo orally daily for 24 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center**

Name of recruitment center

Gastroenterology and Liver Diseases clinic

Full name of responsible person

Behzad Hatami

Street addressGastroenterology and Liver Diseases clinic, Research
Institute of Gastroenterology & Liver Diseases,
Taleghani Hospital, Arabi St. Daneshjo Blvd, Yaman
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadreza Zali

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Diseases, Taleghani Hospital, Arabi St. Daneshjo Blvd,
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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

Shahid Beheshti University of Medical Sciences

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behzad Hatami

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterologist

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Kaveh Baghaei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Helia Alavifard

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Laboratory Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of data which is related to main outcome could be
share

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

starting in 2021

To whom data/document is available

It would be available for people working in academic
institutions and those are in businesses can also apply to
receive it.

Under which criteria data/document could be used

It is depend on requests.

From where data/document is obtainable

Corresponding: Dr. Behzad Hatami
"bhz_hatami@yahoo.com" Dr. Kaveh Baghaei
"kavehbaghai@gmail.com"

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

-Request - Early consideration in 1 week - Conversations
- Provide possible request between 2-4 weeks

Comments