

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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)

##### Phone

+98 21 2243 2516

##### Email address

kavehbaghaei@sbm.ac.ir

##### 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. CCTC 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 C<sub>29</sub>H<sub>31</sub>N<sub>7</sub>O. 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 address**

Gastroenterology and Liver Diseases clinic, Research Institute of Gastroenterology & Liver Diseases, Taleghani Hospital, Arabi St. Daneshjo Blvd, Yaman St. Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985714711

**Phone**

+98 21 2243 2516

**Email**

bzd\_hatami@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammadreza Zali

**Street address**

Research Institute of Gastroenterology & Liver Diseases, Taleghani Hospital, Arabi St. Daneshjo Blvd, Yaman St. Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985714711

**Phone**

+98 21 2243 2525

**Email**

nnezali@hotmail.com

**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

**Street address**

Research Institute of Gastroenterology & Liver Diseases, Taleghani Hospital, Arabi St. Daneshjo Blvd, Yaman St. Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985714711

**Phone**

+98 21 2243 2516

**Email**

bzd\_hatami@yahoo.com

**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

**Street address**

Research Institute of Gastroenterology & Liver Diseases, Taleghani Hospital, Arabi St. Daneshjo Blvd, Yaman St. Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985714711

**Phone**

+98 21 2243 2516

**Fax****Email**

kavehbaghaei@sbmu.ac.ir

**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

**Street address**

Gastroenterology and Liver Diseases clinic, Research Institute of Gastroenterology & Liver Diseases, Taleghani Hospital, Arabi St. Daneshjo Blvd, Yaman St. Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1985714711

**Phone**

+98 21 2243 2516

**Fax**

**Email**

alavifardh@yahoo.com

## 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**