

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Impact of imatinib on reducing the painful crisis in patients with sickle cell disease

#### Protocol summary

##### Study aim

Evaluation of the effect of Imatinib on painful crisis of Patients with sickle cell anemia

##### Design

Phase 1 and 2 study on 10 patients and evaluation of the before and after effects of the drug

##### Settings and conduct

This study will be conducted on patients with severe refractory sickle cell anemia in hematology clinics of Shiraz University of Medical Science. The patients will be entered the study for one year after obtaining informed consent and explanations about Imatinib and its possible side effects. The patients will be excluded from the study if they do not tolerate the drug, declare dissatisfaction or show side effects.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with severe sickle cell anemia unresponsive to hydroxyurea. exclusion criteria: allergy to imatinib or addiction

##### Intervention groups

Intervention group: Prescription of Imatinib, made by Osveh, to patients with refractory sickle cell anemia, 100 mg 3 times per day and evaluation of the beneficial or untoward effect of it. Study duration is about one year.

##### Main outcome variables

Number of painful crisis per year in each patient, Total number of hospitalization due to painful crisis per year per patient

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131106015305N2**

Registration date: **2020-12-01, 1399/09/11**

Registration timing: **retrospective**

Last update: **2020-12-01, 1399/09/11**

Update count: **0**

##### Registration date

2020-12-01, 1399/09/11

##### Registrant information

###### Name

Mojtaba Karimi

###### Name of organization / entity

Shiraz University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1623 2937

###### Email address

mjkarimi@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2014-04-04, 1393/01/15

##### Expected recruitment end date

2015-04-05, 1394/01/16

##### Actual recruitment start date

2014-04-05, 1393/01/16

##### Actual recruitment end date

2014-09-23, 1393/07/01

##### Trial completion date

2020-03-20, 1399/01/01

##### Scientific title

Impact of imatinib on reducing the painful crisis in patients with sickle cell disease

##### Public title

Impact of imatinib on reducing the painful crisis in patients with sickle cell disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

patients with sickle cell syndromes have at least 3 painful crisis or more per year despite adherence to their standard treatment i.e. hydroxyurea

**Exclusion criteria:**

allergy to imatinib addiction to opioids

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

No information

**Sample size**

Target sample size: **10**

Actual sample size reached: **8**

**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**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences, Zand Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Approval date**

2014-07-28, 1393/05/06

**Ethics committee reference number**

IR.SUMS.REC.1393.4092

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

Sickle cell anemia

**ICD-10 code**

D57

**ICD-10 code description**

Sickle-cell disorders

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

Number of painful crisis per year in each patient

**Timepoint**

Before intervention and every 1 month for a year

**Method of measurement**

Patients self report, Hospitalization record, The amount of analgesic used per month in each patient

**2****Description**

Total number of hospitalization due to painful crisis per year per patient

**Timepoint**

Before study and then every 1 months for 1 years

**Method of measurement**

Patients self report, Hospitalization record

**Secondary outcomes**

empty

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

Intervention group: Administration of Imatinib, made by Osveh, 100mg three times per day , to continue for one year

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Namazi hospital

**Full name of responsible person**

Mojtaba Karimi

**Street address**

Namazi hospital, Zand square

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**Province**

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**Phone**

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**Email**

mjkarimi@sums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Abbas Rezaianzadeh

**Street address**

Research deputy, Shiraz University of Medical Sciences, Zand Blvd

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**Province**

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**Phone**

+98 71 3235 7282

**Email**

rezaiana@sums.ac.ir

**Web page address**

<https://research.sums.ac.ir/page-researchm/fa/205/form/pld28590>

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mojtaba Karimi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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Ward of Internal Medicine, Namazi Hospital, Zand Blvd

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mojtaba Karimi

**Position**

Assistant professor

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## **Sharing plan**

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

No - There is not a plan to make this available

### **Justification/reason for indecision/not sharing IPD**

There is no further information

### **Study Protocol**

No - There is not a plan to make this available

### **Statistical Analysis Plan**

No - There is not a plan to make this available

### **Informed Consent Form**

No - There is not a plan to make this available

### **Clinical Study Report**

No - There is not a plan to make this available

### **Analytic Code**

No - There is not a plan to make this available

### **Data Dictionary**

No - There is not a plan to make this available