

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The efficacy of L- glutamine in the control of crisis event in patients with sickle cell and sickell thalassemia

#### Protocol summary

##### Study aim

evaluation of patients with sickle cell and sickell thalassemia after treatment with l-glutamin

##### Design

Randomised 15 patients were studied.

##### Settings and conduct

an outpatient patient will receive a L-glutamine of 10 to 30 grams per day, and the rate of pain crisis was assessed before the intervention, at the end of the fourth week and the eighth week.

##### Participants/Inclusion and exclusion criteria

patients with sickle cell and sickell thalassemia -renal impairment- kidney imparment-HB<5 gr -need to emergengy transfusion- pregnancy - admition more than 10 times -sensivity to l glutamin

##### Intervention groups

L-glutamin drug

##### Main outcome variables

crisis event at the end of the fourth week and the eighth week.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180603039959N1**

Registration date: **2020-01-10, 1398/10/20**

Registration timing: **retrospective**

Last update: **2020-01-10, 1398/10/20**

Update count: **0**

##### Registration date

2020-01-10, 1398/10/20

##### Registrant information

##### Name

bijan keikhaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3375 0410

##### Email address

keikhaeib@yahoo.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-06-21, 1397/03/31

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of L- glutamine in the control of crisis event in patients with sickle cell and sickell thalassemia

##### Public title

The efficacy of L- glutamine in sickle cell and sickell thalassemia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

patients with sickle cell and sickell thalassemia

##### Exclusion criteria:

Kidney impairment Renal impairment HB <5 gr Need to emergency transfusion Pregnancy Admition more than 10 times Sensivity to glutamin

##### Age

No age limit

##### Gender

Both

### Phase

2

### Groups that have been masked

No information

### Sample size

Target sample size: 15

### 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 ahvaz Jondyshapur University of Medical

##### Street address

golestan ave-baghayi hospital

##### City

ahvaz

##### Province

Khuzestan

##### Postal code

61357-15794

#### Approval date

2018-05-11, 1397/02/21

#### Ethics committee reference number

IR.AJUMS.REC.1397.121

## Health conditions studied

### 1

#### Description of health condition studied

sickle cell and sickell thalassemia

#### ICD-10 code

D57

#### ICD-10 code description

Sickle-cell disorders

## Primary outcomes

### 1

#### Description

effect to crisis event

### Timepoint

at the end of fourth and eighth week

### Method of measurement

pain-admission times-crisis

## Secondary outcomes

### 1

#### Description

crisis event

#### Timepoint

at the end of fourth and eight weeks

#### Method of measurement

Face Pain Scale

## Intervention groups

### 1

#### Description

15 patient with sickle cell and sickell thalassemia that have slection criteria were selected.In this study, an outpatient patient will receive a L-glutamine of 10 to 30 grams per day, and rate of crisis was assessed before the intervention, at the end of the fourth week and the eighth week.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baghayi 2 Hospital

##### Full name of responsible person

Neda Farmani Anooshe

##### Street address

Golestan Blvd-Baghayi hospital 2

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

61357-15794

##### Phone

+98 61 3375 0410

##### Fax

##### Email

nedafarmanianoosheh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mohammad Bdavi

**Street address**

Baghayi hospital

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357-15794

**Phone**

+98 61 3375 0410

**Email**

nedafarmanianoosheh@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Neda Farmani Anooshe

**Position**

assistant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

**Street address**

Baghayi Hospital

**City**

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**Province**

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**Phone**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Neda Farmani Anoosheh

**Position**

assistant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

**Street address**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Neda Farmani Anooshe

**Position**

assistant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

**Street address**

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**City**

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**Province**

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**Postal code**

61357-15794

**Phone**

+98 41 3336 1658

**Email**

nedafarmanianoosheh@gmail.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

Undecided - It is not yet known if there will be 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

**Title and more details about the data/document**

there is no plan for republication

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

there is no plan for republication

**To whom data/document is available**

there is no plan for republication

**Under which criteria data/document could be used**

there is no plan for republication

**From where data/document is obtainable**

there is no plan for republication

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

there is no plan for republication

**Comments**