

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Investigating the effectiveness of L-arginine in reducing duration of hospitalization and pain intensity of children with sickle cell disease compared to placebo.

#### Protocol summary

##### Study aim

Investigating the effectiveness of L-arginine in reducing duration of hospitalization and pain intensity of children with sickle cell disease compared to placebo.

##### Design

Pragmatic, community based, parallel group, double blind, randomised controlled trial

##### Settings and conduct

This study will be done in the hematology ward Shafa Hospital of Ahvaz. This study will be a double blind trial that patients and nurses will be blinded to the type of interventions. Blinding technique will be same in shape, color, size and taste in the study group.

##### Participants/Inclusion and exclusion criteria

Inclusion: Patients affected by Sickle cell between the ages of 3 to 20 years old. Exclusion: liver failure; renal failure under 5 grams of hemoglobin per deciliter; patients in need of immediate infusion of blood; pregnancy; history of hospitalization more than 10 times in the hospital; a history of opiate dependence; sensitivity to arginine

##### Intervention groups

L-arginine group: 100 mg/kg IV or oral, 3 times per day.  
Placebo group: 100 mg/kg IV or oral 3 times per day.

##### Main outcome variables

Reduced hospitalization time; Reduced pain intensity in sickle cell patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170112031891N2**  
Registration date: **2018-04-09, 1397/01/20**  
Registration timing: **retrospective**

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

##### Registration date

2018-04-09, 1397/01/20

##### Registrant information

###### Name

Nima Mahmoudzadeh

###### Name of organization / entity

Jundishapoor University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

-

###### Email address

mahmoudzadeh.n@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Jundishapoor University of Medical Sciences

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-01-20, 1396/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effectiveness of L-arginine in reducing duration of hospitalization and pain intensity of children with sickle cell disease compared to placebo.

##### Public title

Investigating the effectiveness of L-arginine in reducing duration of hospitalization and pain intensity of children

with sickle cell disease compared to placebo.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients affected by sickle cell disease Age 3 to 20 years

**Exclusion criteria:**

liver failure Renal failure Under 5 grams of hemoglobin per deciliter Patients in need of immediate infusion of blood Pregnancy History of hospitalization more than 10 times in the hospital A history of opiate dependence Sensitivity to arginine

**Age**

From **3 years** old to **20 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Based on the 6-block method, individuals will be divided randomly into two equal groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, patients and nurses who prescribed medications to patients are blinded to the type of drugs. The main drug and placebo are the same in terms of shape, size, taste and packaging. The physician that collect treatment outcomes will not be blinded about allocation of interventions.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

-

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Golestan street, Shahr Daneshgahi, Deputy of Research and Technology Development of Ahvaz Jondishapur University of Medical Sciences, Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357-15794

**Approval date**

2017-05-27, 1396/03/06

**Ethics committee reference number**

ir.ajums.rec.1396.190

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

Sickle cell disease

**ICD-10 code**

D57.81

**ICD-10 code description**

Other sickle-cell disorders with crisis

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

Pain

**Timepoint**

A week

**Method of measurement**

Based on Visual Analogue Scale and Faces Pain

**2****Description**

Time of Hospitalization

**Timepoint**

The duration of treatment

**Method of measurement**

The duration of Hospitalization

**Secondary outcomes****1****Description**

Pharmaceutical allergy

**Timepoint**

The duration of treatment

**Method of measurement**

Clinical observation

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

L-arginine drug orally or intravenously at a dose of 100 mg / kg, three times a day until discharge from hospital

**Category**

Treatment - Drugs

**2**

**Description**

Placebo drug orally or intravenously at a dose of 100 mg / kg, three times a day until discharge from hospital

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shafa Hospital

**Full name of responsible person**

Dr. Nima Mahmoudzadeh

**Street address**

Golestan street, Shafa Hospital, Ahvaz, Khuzestan Province, Iran

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3155

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itc@ajums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Arash Alqasi

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<http://vchresearch.ajums.ac.ir>

**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**

Dr Nima Mahmoudzadeh

**Position**

Resident of Pediatrics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Golestan street, Pediatrics ward, Golestan hospital, Ahvaz, Khuzestan Province, Iran

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Arash Alqasi

**Position**

Pediatrics Hematologist Sub-Specialist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr Nima Mahmoudzadeh

**Position**

Resident of Pediatric Disease

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

Golestan street, Pediatrics ward, Golestan hospital,  
Ahvaz, Khuzestan Province, Iran

**City**

Ahvaz

**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**

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**

Undecided - It is not yet known if there will be 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