

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

City

Ahvaz

Province

Khuzestan

Postal code

3155

Phone

+98 61 3743 2813

Email

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

Street address

Golestan street, Shahr daneshgahi, Deputy of Research and Technology Development of Jundishapur University of Medical Sciences Ahvaz, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

06133361544

Phone

+98 61 3336 2414

Email

itc@ajums.ac.ir

Web page address

<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

City

Ahvaz

Province

Khuzestan

Postal code

33118-61357

Phone

+98 61337430019

Fax

+98 61 3374 3030

Email

Nima87433@yahoo.com

Web page address

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

Street address

Golestan street, Pediatrics hematology ward, Shafa

hospital, Ahvaz, Khuzestan Province, Iran

City

Ahvaz

Province

Khuzestan

Postal code

33118-61357

Phone

+98 613374328

Fax

+98 61 3374 3289

Email

arashalqasi@yahoo.com

Web page address

Province

Khuzestan

Postal code

33118-61357

Phone

+98 61337430019

Fax

+98 61 3374 3030

Email

Nima87433@yahoo.com

Web page address

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