

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

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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

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Ahvaz

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Subspecialist

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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