

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The Effect of Non Pharmacological Palliative Methods Education on the Severity of Pain and Referring Rate of Adolescences with Sickle cell Anemia

Protocol summary

Study aim

determining the Effect of Non-pharmacological Palliative Method Education on Pain Severity and the Rate of Referring in Adolescents with Sickle cell Anemia

Design

Parallel Group Trial, one-blinded with Intervention and Control Group Which Randomly Assigned to Six Blocks .

Settings and conduct

The study will be carried out at The Ahvaz shafa Hospital and the use of Non-pharmacological Pain Relief Methods at the time of the onset of pain. Clients will enter the study according to entry criteria and provide them with the necessary Training During 4 sessions, and They will be asked to repeat and practice techniques at home and use them at the time of pain.

Participants/Inclusion and exclusion criteria

-Aged 12-18 years -Repeat visits to the clinic or admission to the hospital due to pain (at least once a year) -They have not received any pain care education. - Members use only oral Analgesics such as acetaminophen or Ibuprofen.

Intervention groups

60 adolescents With Sickle cell Anemia will be divided into two groups of intervention and control.

Main outcome variables

severity of pain; number of visits

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180128038531N1**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

Registration date

2018-04-21, 1397/02/01

Registrant information

Name

fatemeh maniavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Non Pharmacological Palliative Methods Education on the Severity of Pain and Referring Rate of Adolescences with Sickle cell Anemia

Public title

study of The effect non-pharmacological Palliative Method on severity of pain and the rate of referral to the clinic in Adolescences with sickle cell

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Non-acute and chronic physical and mental illness Not having mental-emotional disturbances A history of frequent visits to the clinic or admission to the hospital due to pain (at least once a year) Failure to receive Pain Care Education in advance Use only oral hygiene drugs such as acetaminophen or profen.

Exclusion criteria:

Age
From **12 years** old to **21 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Block Method using six Blocks

Blinding (investigator's opinion)
Single blinded

Blinding description
The Study is one-sided type so that the person evaluating the results of the study is kept unaware of the type of treatment group in each patient.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Department of Research and Technology Development, Academic City, Jundishapur University of Medical Sciences

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Ahvaz

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Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

879.IR.AJUMS.REC.1396

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

pain severity

Timepoint

4 Weeks before Training

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Reduce referring

Timepoint

4 and 8 weeks after training

Method of measurement

Patient report

Intervention groups

1

Description

In the intervention group, there were 30 adolescents with sickle cell disease who have been trained in non-pharmacological palliative care and who are required to apply the methods for 8 weeks, during which time they recorded the severity of pain and referral to the clinic or hospital for pain. Finally, the effect of applying these methods on the severity of pain and the number of referrals due to pain is evaluated by the researcher.

Category

Prevention

2

Description

Control group: In the Control group, there were 30 adolescents suffering from sickle cell Disease, who do not receive any pain relief training in the field of non-pharmacological methods, record only the severity of pain and the cases of referral to the clinic or hospital due to pain, and care is routinely done.

Category

Other

Recruitment centers1**Recruitment center****Name of recruitment center**

Shafa Hospital

Full name of responsible person

Rostami Shahnaz

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Rostami Shahnaz

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact**

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Full name of responsible person

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Nursery

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

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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