Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of the P6 Acupressure on the amount of anxiety and the intensity of the pain caused by the venipuncture in patients with Thalassemia

Protocol summary

Study aim
Evaluation of the Effect of the P6 Acupressure on the amount of anxiety and the intensity of the pain caused by the venipuncture in patients with Thalassemia who admitted in Cooley’s ward

Design
A randomized controlled clinical trial with parallel groups, without blinding, 80 patients

Settings and conduct
This study will be performed on thalassemic patients admitted to the collision ward of Shahid Beheshti Hospital of Yasuj University of Medical Sciences. After obtaining permission during the data gathering phase, the researcher divides patients into two groups of experimental and control. Anxiety was measured in both groups before the venipuncture using Spielberger questionnaire. In the experimental group, point P6 will be used for acupressure. During the intervention, the researcher assesses and records the patient's pain. Then, after intervention, the patient's anxiety level was reassessed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Ability to communicate and answer questions 2- Consent to participate in the study and sign the informed consent form Exclusion criteria: 1- Patient's dissatisfaction with the study 2. Failure of a vein to be successful or need to be repeated 3 - taking analgesics within 3 hours before or during the study 4. Receive another painful intervention while the angiocut is embedded 5- Use of hypnotic, anxiolytic and antidepressant drugs before intervention

Intervention groups
Intervention group consisting of P6 Acupressure on the amount of anxiety and the intensity of the pain caused by the venipuncture in patients with Thalassemia who admitted in Cooley’s ward Control group included of P6 Acupressure on the amount of anxiety and the intensity of the pain caused by the venipuncture in patients with Thalassemia who admitted in Cooley’s ward

Main outcome variables
The amount of anxiety and the intensity of the pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200109046066N1**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date
2020-03-14, 1398/12/24

Registrant information

Name
Saeideh Avini athar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 74 3333 5651

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-08, 1398/11/19

Expected recruitment end date
2020-04-18, 1399/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of the P6 Acupressure on the amount of anxiety and the intensity of the pain caused by the venipuncture in patients with Thalassemia

Public title
Effect of the P6 Acupressure on the amount of anxiety and the intensity of the pain caused by the venipuncture in patients with Thalassemia

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Ability to communicate and answer questions Consent to participate in the study and sign the informed consent form

Exclusion criteria:
Patient's dissatisfaction with the study Failure of venipuncture or need to be reunited taking analgesics within 3 hours before or during the study Receive another painful intervention while the angiocut is embedded Use of hypnotic, anxiolytic and antidepressant drugs before intervention

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Yasuj University of Medical Sciences

Street address
Farei 1 alley, Friday Market Ave, Yasuj

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591616113

Approval date
2020-01-25, 1398/11/05

Ethics committee reference number
IR.YUMS.REC.1398.148

Health conditions studied

1

Description of health condition studied
Patients with thalassemia

ICD-10 code
D56.1

ICD-10 code description
Beta thalassemia

Primary outcomes

1

Description
Anxiety score in Spiegel Berger questionnaire

Timepoint
Anxiety levels before and after the intervention

Method of measurement
Spielberger’s State-Trait Anxiety Inventory (STAI)

2

Description
Pain score based on visual analogue scale(VAS)

Timepoint
Severity of pain during and after the intervention

Method of measurement
Visual Analogue Scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Spielberger questionnaire will be completed before venipuncture. The intervention will be done using acupressure point P6. The P6 point is located on the inner side of the arm and in the cavity between the forearm bones about three fingers wide above the wrist. In order to intervene, pressurize to the point 3 to 5 kg bilaterally in both hands, for 3 minutes with the thumb, 3 minutes each, and 2 minutes rest, rotating and two rounds per second. To be. So that the patient feels a tingling and numbness in his hand. Then, using standard points, an angiocut (pink,

size 20) is inserted for all patients, while the researcher assesses and records the patient's pain with a visual pain scale. Then, after the intervention, the patient's anxiety level will be re-measured.

Category

Treatment - Other

2

Description

Control group: According to the routine procedure, angiocut insertion is performed according to the required standard and, like the intervention group, the patient's pain is measured before and after the operation, anxiety and after the procedure.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Collision, Shahid Beheshti Hospital, Yasuj University of Medical Sciences

Full name of responsible person

Saeideh Avini athar

Street address

Shahid Beheshti Hospital, Shahid Mohammad Montazeri Street, Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Mari Oryad

Street address

Yasuj- Shahid Motahari Boulevard- Yasuj University of Medical Sciences

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oryad.hossein@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Saeideh Avini athar

Position

M.S student of internal surgery nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Farei 1 alley, Friday Market Ave, Yasuj

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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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