

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

saeideh.avini@yahoo.com

##### 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

Kohgiluyeh-va-Boyerahmad

## 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

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyr Ahmad

**Postal code**

7591794857

**Phone**

+98 74 3322 4721

**Fax**

+98 74 3322 1811

**Email**

beheshtihospital@yasooj.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Hossein Mari Oryad

**Street address**

Yasuj- Shahid Motahari Boulevard- Yasuj University of  
Medical Sciences

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyr Ahmad

**Postal code**

7591616113

**Phone**

+98 74 3334 6078

**Fax**

+98 74 3333 7230

**Email**

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**

Yasuj 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**

Yasuj 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

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyr Ahmad

**Postal code**

7591616113

**Phone**

+98 74 3333 5651

**Email**

saeideh.avini@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasuj University of Medical Sciences

**Full name of responsible person**

Saeideh Avini athar

**Position**

M.S student of internal surgery nursing

**Latest degree**

Bachelor  
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Nursery  
**Street address**  
Farei 1 alley, Friday Market Ave, Yasuj  
**City**  
Yasuj  
**Province**  
Kohgilouyeh-va-Boyrahmad  
**Postal code**  
7591616113  
**Phone**  
+98 74 3333 5651  
**Email**  
saeideh.avini@yahoo.com

## Person responsible for updating data

### 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**  
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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