

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigating impact of foot reflexology massage on pain and fatigue in major thalassemic patient

Protocol summary

Study aim

impact of foot massage (reflexology) on fatigue and pain in patients with Thalassemia

Design

This study is a randomized double-blind clinical trial, that will be done on 105 Thalassemia major patients. There are three study groups including: Intervention1(reflexology) , intervention 2(simple touch) and control

Settings and conduct

This research will be carried out on 105 thalassemic patients at Iranshahr Special Disease center. The studied groups include foot reflexology; touch (placebo) and control groups. patients and variable evaluator (researcher assistant) have no information about patients allocation to the groups . Intervention will be done by patients themselves and assessment will be done by researcher assistant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: thalassemic patients that refereed to Iranshahr Special Disease Center; age over 18 years old. Non-inclusion criteria: specific skin disorder such as cellulite and burn at massage area; mental disorder; cognitive and mental illness.

Intervention groups

Intervention group 1: foot reflexology massage will be executed in this group of patients by themselves. Intervention group 2 : the simple touch on sole of foot will be executed in this group of patients by themselves. Control group : no intervention.

Main outcome variables

Pain; Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042906N1**

Registration date: **2019-05-27, 1398/03/06**

Registration timing: **prospective**

Last update: **2019-05-27, 1398/03/06**

Update count: **0**

Registration date

2019-05-27, 1398/03/06

Registrant information

Name

Abdollah Dakkalirad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-04, 1398/03/14

Expected recruitment end date

2019-07-04, 1398/04/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating impact of foot reflexology massage on pain and fatigue in major thalassemic patient

Public title

Effect of foot reflexology massage in thalassemic patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged over 15 years old

Exclusion criteria:
cognitive and mental disorder skin disease such as cellulitis and burn in massage area

Age
From **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization type is stratified randomization that will be done base on pain and fatigue classes (in two classes:moderate and severe). The selection of first sample will be by drawn numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients (samples) are unaware about that they are in which group (intervention 1 - intervention 2 (placebo) and control). In addition, the person who fills the questionnaire (researcher assistant) does not know that the patient is from which group (intervention1 - intervention 2 (placebo) -control).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committe of Rafsanjan University of Medical sciences

Street address
Rafsanjan University of Medical science, Imam Ali Ave

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2019-03-04, 1397/12/13

Ethics committee reference number
IR.RUMS.REC.1397.240

Health conditions studied

1

Description of health condition studied
Major Thalasemia

ICD-10 code
D56

ICD-10 code description
Thalassemia

Primary outcomes

1

Description
Pain

Timepoint
Before the intervention and after the intervention and two week after intervention

Method of measurement
numeric rating scale

2

Description
fatigue

Timepoint
Before the intervention and after the intervention and two week after intervention

Method of measurement
fatigue severity scale

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description
Intervention group1: The foot reflexology massage will be done by the patient himself on foot reflectic points for ten minutes in every other day, for two weeks.

Category
Treatment - Other

2

Description
Intervention group2 (placebo): the simple foot touch will

be done by the patient himself for ten minutes in every other day, for two weeks.

Category

Placebo

3

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranshahr Special Disease center

Full name of responsible person

Abdollah Dakkalirad

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Iranshahr Special Disease center, Emam Khomeini 48 blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan 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

Rafsanjan 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

Iranshahr University of Medical Sciences

Full name of responsible person

عبدالله دكالى راد

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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