Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of effect of applying tetracaine 4% gel and evaporative anesthesia spray on the intensity of pain caused by blood intravenous injection in patients with thalassemia

Protocol summary

Summary

The aim of this study was to compare the effect of tetracaine 4% gel and evaporative anesthesia spray to reduce the pain of intravenous blood injection. This study is an interventional study and of a randomized clinical trial type that will be done on patients with thalassemia. The population of the study consists of patients with thalassemia visiting thalassemia center. Inclusion criteria for this study: patients 12 to 40 years that well understand the concept of numbers, and are not affected with contextual disease. Exclusion criteria: dispensing with participating in the study, being with side effects in venipuncture. In this study, after determining the sample size based on similar studies 90 patients who have the criteria to participate in the study are selected and we divide treatment between them randomly into three groups of 30 with random block division method. In the first group, Tetracaine 4% gel will be used in 3 grams in an area with the size of 10 cm square with a light dressing for 30 minutes before intravenous injection and then gels are cleaned and injection will take place. In the second group, evaporative spray will be used; in this way that it will be sprayed out at room temperature by a researcher from a distance of 25 cm for 5-10 seconds until being the skin white and pale and then because of a short effect of 30-40 seconds later the injection will be carried out. In the third group, the injection will be done with no interventional agent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112219862N3**
Registration date: **2017-05-13, 1396/02/23**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-05-13, 1396/02/23

Registrant information

Name

Sakine Sabzevari

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2016-12-15, 1395/09/25

Expected recruitment end date

2017-01-14, 1395/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effect of applying tetracaine 4% gel and evaporative anesthesia spray on the intensity of pain caused by blood intravenous injection in patients with thalassemia

Public title

The effect of tetracaine 4% gel and evaporative spray on reducing the pain of intravenous blood injection in patients with thalassemia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients 12 to 40 years; Have file from the Thalassemia Center; Satisfaction of participate in the study; Insensitivity to use any of the intervention; Full awareness of time; Place and person. Exclusion criteria: Patients who have suffered physical and psychological problems and drugs that reduce pain and anxiety consume; Do not understand the concept of numbers; An underlying disease such as diabetes and Login more than once catheter.

Age

From **12 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

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

Kerman University of Medical Sciences Ethics Commitee

Street address

Razi School of Nursing And Midwiferi, Haftbaq Alavi Street, Kerman

City

Kerman

Postal code

Approval date

2016-09-21, 1395/06/31

Ethics committee reference number

IR.KMU.REC.1395.95

Health conditions studied

1

Description of health condition studied

Thalassemia

ICD-10 code

D56

ICD-10 code description

Thalassaemia

Primary outcomes

1

Description

intensity of pain

Timepoint

Immediately after the intervention

Method of measurement

Numerical scale (NRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Groups: 1) Gel: tetracaine gel 4%. amount of 3 grams. An area of 10 square centimeters. for 45 minutes.

Category

Treatment - Drugs

2

Description

Intervention Groups: 2) spray: Spray evaporate, at a distance of 25 cm from the site of injection for 5 to 10 seconds

Category

Treatment - Drugs

3

Description

Control Group: No interventio

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Aboureihan Specific Disease Center

Full name of responsible person

Seyedeh Fatemeh Pourseyed Larzjani/Masters student

Street address
Aboureihan Specific Disease Center, Shafa Blvd.Bandaabbas
City
Bandarabbas

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhty/PhD in Pharmaceutics
Street address
Razi School of Nursing And Midwiferi, Haftbaq Alavi Street, Kerman
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code

empty

Data Dictionary

empty