Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The evaluation of effect of cold application over skin on the change of pain level during the injection of local anesthetic drugs in patients with skin laceration

Protocol summary

Summary

The objective of the study is to evaluate the effect of local cold application on the the pain produced by the injection of local anesthetic drug. 90 people referring to Rasoul Akram and Sian emergency departments who have found laceration anywhere in their skin. First, the pain level of injured area will be measured by visual analogue scale (VAS) score. Then, the patients will be divided to case and control groups by numerical random scale. Cold will be applicated over the affected area for 5 minutes just for the case group. Then, 1% lidocain solution will be injected through a 20 G needle to anesthesize the area. The pain produced by injection will be measured again by VAS score and will be compared to the initial pain. The change in pain level will be compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307238543N4**
Registration date: **2014-11-28, 1393/09/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-28, 1393/09/07

Registrant information

Name

Babak Mahshidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Iran University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effect of cold application over skin on the change of pain level during the injection of local anesthetic drugs in patients with skin laceration

Public title

The effect of cold application on the skin upon the pain produced by the injection of local anesthetic drugs.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: acute skin laceration needing local anesthetic injection; age over 8 Exclusion criteria: Intolerable and intense pain; having severe injuries and fractures in other sites of the body; serious and extensive skin illness; neurological or psychological disorders; use of other local or systemic sedative drugs; skin allergy to cold

Age

No age limit

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

Iran University of Medical Sciences

Street address

Medical College, Hemmat Highway

City

Tehran

Postal code

Approval date

2013-08-23, 1392/06/01

Ethics committee reference number

8635

Health conditions studied

1

Description of health condition studied

pain of injection of local anesthetic drugs.

ICD-10 code

S01, S11,

ICD-10 code description

Open wound of head, Open wound of neck, Open wound of thorax, Open wound of abdomen, lower back and pelvis, Open wound of shoulder and upper arm, Open wound of forearm, Open wound of wrist and hand, Open wound of hip and thigh, Open wound of lower leg, O

Primary outcomes

1

Description

Pain Severity

Timepoint

Before, during and after administration of Ice compress

Method of measurement

Administration of Visual Analogue Scale

Secondary outcomes

1

Description

increase of pain

Timepoint

post intervention

Method of measurement

visual analog scale

Intervention groups

1

Description

in intervention group, dry ice will be used for 5 minutes on the wound site.

Category

Other

2

Description

control group will not receive any intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Hazrate Rasool (S) Educational-Therapeutic Centre

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Emergency Department of Haft-e-Tir Hospital

Full name of responsible person

Street address

City

Tehran

3

Recruitment center
Name of recruitment center
Emergency Department of Firoozgar Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi. MD
Street address
Hemmat Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Iran 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
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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*