

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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 anesthize 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)

##### Phone

+98 21 6435 2221

##### Email address

b-mahshidfar@tums.ac.ir

##### 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

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Babak Mahshidfar

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Hazrat Rasool Hospital, Niayesh St. Satarkhan st.

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### Person responsible for scientific inquiries

#### Contact

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Assistant Professor of Emergency Medicine

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### Person responsible for updating data

#### Contact

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**Full name of responsible person**

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Assistant Professor of Emergency Medicine

**Other areas of specialty/work**

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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*

