

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of pain score and satisfaction with wound healing in two groups receiving intravenous ibuprofen infusion and placebo in emergency department

Protocol summary

Study aim

The purpose of this study was to compare the pain and satisfaction of patients with wound healing in two groups receiving intravenous ibuprofen infusion and placebo.

Design

The design of the study is a randomized clinical trial. The randomization method is blocked. The sample size for each study group is 75.

Settings and conduct

In this research, all patients referred to the to the Emergency Department of Shohada-e- Haftome tir Hospital who are with skin laceration with a minimum wound length of 2 cm, included in the study. Patients will be randomly divided into two groups based on 10 blocks. A total of 150 patients will be examined. All patients and data analyzers will be blind.

Participants/Inclusion and exclusion criteria

All patients referred to the Emergency Department of Shohada-e- Haftome tir Hospital who are wounded and over the fifteen years old and under the seventy five years old are enrolled. Inclusion criteria: Patients with skin laceration with a minimum wound length of 2 cm. Exclusion criteria: Patients with ischemic heart disease. Patients with decreased consciousness. Patients Burning by Animals.

Intervention groups

In the intervention group, before the wound healing, 800 mg ibuprofen in 200 ml of normal saline will be injected, and in the control group, 200 ml normal saline without medication will be injected.

Main outcome variables

The severity of the patient's pain before the injection; the severity of the patient's pain after the injection; patient satisfaction before wound healing; patient satisfaction during wound healing; patient satisfaction after wound healing.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120613010017N8**

Registration date: **2018-11-28, 1397/09/07**

Registration timing: **prospective**

Last update: **2018-11-28, 1397/09/07**

Update count: **0**

Registration date

2018-11-28, 1397/09/07

Registrant information

Name

Hamed Basir Ghafouri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pain score and satisfaction with wound healing in two groups receiving intravenous ibuprofen infusion and placebo in emergency department

Public title

Comparison of pain score and satisfaction with wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with skin laceration with a minimum wound length of 2 cm

Exclusion criteria:

Patients with ischemic heart disease Patients with decreased consciousness Patients who are bitten by animals

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups. In order to randomize, a random block method is used. For this purpose, we formed blocks with 10 person. In each block, 5 individuals will be in intervention group and 5 will be in control group. A total of 15 blocks will be considered for sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in the study will be blinded of the type of received intervention. Data analyzer will be blinded of the type of intervention received by patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat highway, Tehran, Iran.

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Province

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Postal code

1449614535

Approval date

2017-06-22, 1396/04/01

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511307013

Health conditions studied

1

Description of health condition studied

Wound repair

ICD-10 code

T81.33

ICD-10 code description

Disruption of traumatic injury wound repair

Primary outcomes

1

Description

The severity of the patient's pain

Timepoint

Before and After injection

Method of measurement

Questionnaire

2

Description

Patient satisfaction

Timepoint

Before wound healing, during wound healing and After wound healing

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 800 mg ibuprofen in 200 ml of normal saline

Category

Treatment - Drugs

2

Description

Control group: Injection 200 ml normal saline without medicine

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e- Haftome tir Hospital

Full name of responsible person

Mohammad Hossein Rezari Dogahe

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Sponsors / Funding sources

1

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Name of organization / entity

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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

Iran 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

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Full name of responsible person

Mohammad Hossein Rezari Dogahe

Position

Emergency Medicine

Latest degree

Specialist

Other areas of specialty/work

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Phone**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