

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of oxycodone and naproxen in pain control of soft tissue injuries

Protocol summary

Summary

Soft tissue injury is a common problem in emergency departments. Pain control is the cornerstone in patient satisfaction and compliance of patients with soft tissue injuries. The effective and safe drugs in pain control have been always interested and this study tries to compare one of the most common drugs used in soft tissue pain control (naproxen) with an oral opioid (oxycodone). This study is a double blind randomized trial which is conducted in an academic emergency department. All patients over 18 years old suspicious to soft tissue injury would be included and randomized in 2 group, Naproxen 500 mg or Oxycodone 10 mg will be given to them orally and their pain score would be followed before, 30 minutes and 60 minutes after receiving the medication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112208104N3**

Registration date: **2012-08-31, 1391/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-31, 1391/06/10

Registrant information

Name

Mohammad Amin Zare

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 5327

Email address

ma-zare@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2012-05-01, 1391/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oxycodone and naproxen in pain control of soft tissue injuries

Public title

Comparison of oxycodone and naproxen in pain control of acute soft tissue injuries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: patients above 18 years old with soft tissue injuries. Exclusion criteria: contraindications for opioids and NSAIDs and presence of fracture.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghods street- Keshavarz blvd-tehran

City

Tehran

Postal code

-

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

130/206/91/3

Health conditions studied

1

Description of health condition studied

soft tissue injuries

ICD-10 code

XIII

ICD-10 code description

musculoskeletal system and connective tissue

Primary outcomes

1

Description

Pain control

Timepoint

0, 30, 60 minutes after treatment

Method of measurement

Numeric Rating Scale

Secondary outcomes

1

Description

Presence of side effects

Timepoint

30 and 60 minutes after treatment

Method of measurement

Patient monitoring

2

Description

Need for follow up analgesic

Timepoint

First 24 hours after discharge

Method of measurement

Telephone follow up

Intervention groups

1

Description

First group will receive 250 mg Naproxen

Category

Treatment - Drugs

2

Description

Second group receive 10 mg Oxycodone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

RASOUL AKRAM HOSPITAL

Full name of responsible person

MOHAMMAD AMIN ZARE

Street address

Emergency Department, Rasoul Akram Hospital,
Niyayesh St; Sattarkhan Ave

City

TEHRAN

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research; Tehran University of
Medical Sciences

Full name of responsible person

Shahin Akhoundzadeh

Street address

Qods Ave, Keshavarz Blvd

City

Tehran
Grant name
-
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research; Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Amin Zare
Position
Assistant Professor
Other areas of specialty/work
Street address
Emergency Department; Rasoul Akram Hospital, Niyayesh St; Satterkhan Ave
City
Tehran
Postal code
14456
Phone
+98 21 6652 5327
Fax
+98 21 6652 5327
Email
mazare74@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Amin Zare
Position
Assistant Professor

Other areas of specialty/work
Street address
Emergency Department, Rasoul Akram Hospital, Niyayesh St; Sattarkhan Ave
City
Tehran
Postal code
14456
Phone
+98 21 6652 5327
Fax
+98 21 6652 5327
Email
mazare74@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Amin Zare
Position
Assistant Professor
Other areas of specialty/work
Street address
Emergency Department, Rasoul Akram Hospital, Niyayesh St; Sattarkhan Ave
City
Tehran
Postal code
14456
Phone
+98 21 6652 5327
Fax
+98 21 6652 5327
Email
mazare74@yahoo.com
Web page address

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