

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Survey of Intravenous Acetaminophen versus intravenous morphin in acut burn pain management

#### Protocol summary

##### Summary

Burn pain management is a major challenge in treating of these patients. In this randomized single blinded interventional study intravenous acetaminophen and intravenous morphine will be compared for pain management in the burns. 150 patients from 15 to 55 years old with 15% to 50% acute burn and indication of admission will be enrolled to our study. Patients with unstable vital signs, altered mental status and substance abuse will be excluded. The Patients will be selected as random allocation AND consecutive sampling and will be divided into 3 equal (50) groups. The first group on the first day will be received IV acetaminophen and in the second day IV morphine. The second group on the first day will be received IV morphine and in the second day IV acetaminophen and the third group will be received IV morphine in the first and second day. Pain intensity will be measured according to visual analog scale one minute before the injection, 30 and 60 minutes after the injection in each group. The mean pain reduction on VAS before and after injection will be compared in tree groups. Morphine dosage: 0.1 mg/kg every 6 hours Acetaminophen dosage: adults over 50 kg: 1 g IV every 6 hours Adults under 50 kg: 15 mg /kg IV every 6 hours

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201101205588N1**  
Registration date: **2011-06-30, 1390/04/09**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-06-30, 1390/04/09

#### Registrant information

##### Name

Karim Sohrabi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 310 1097

##### Email address

sohrabi@alborz.mui.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran university of medical sciences

#### Expected recruitment start date

2011-02-04, 1389/11/15

#### Expected recruitment end date

2011-07-06, 1390/04/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Survey of Intravenous Acetaminophen versus intravenous morphin in acut burn pain management

#### Public title

effect of intravenous acetaminophen on pain manegement

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria:Second or more degree of burn;Burn at least 15% total body surface area AND maximum 50% total body surface area;Hospitalization at least for 2 days;Stable vital signs and ASA I AND ASA II conditions.

Exclusion criteria: Drug abuse and addiction; Unstable vital signs; loss of consciousness; respiratory distress; Pneumothorax or suspicion to that; Bowel obstruction or suspicion to that; Pneumocephalus; Asthma AND COPD AND IHD; Discharged patients by informed consent in less than 2 days of hospitalization; Active chronic liver disease.

## Age

From **15 years** old to **55 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Crossroad of Hemmat AND Fazl-allah Expway

##### City

Tehran

##### Postal code

#### Approval date

2010-11-23, 1389/09/02

#### Ethics committee reference number

152

## Health conditions studied

### 1

#### Description of health condition studied

burn

#### ICD-10 code

T30.2

#### ICD-10 code description

Burn of second degree, body region unspecified

### 2

#### Description of health condition studied

burn

#### ICD-10 code

T30.3

#### ICD-10 code description

Burn of third degree, body region unspecified

### 3

#### Description of health condition studied

burn

#### ICD-10 code

T31.1

#### ICD-10 code description

Burns involving 10-19% of body surface

### 4

#### Description of health condition studied

burn

#### ICD-10 code

T31.2

#### ICD-10 code description

Burns involving 20-29% of body surface

### 5

#### Description of health condition studied

burn

#### ICD-10 code

T31.3

#### ICD-10 code description

Burns involving 30-39% of body surface

### 6

#### Description of health condition studied

burn

#### ICD-10 code

T31.4

#### ICD-10 code description

Burns involving 40-49% of body surface

### 7

#### Description of health condition studied

burn

#### ICD-10 code

T31.5

#### ICD-10 code description

Burns involving 50-59% of body surface

## Primary outcomes

### 1

#### Description

Pain severity

#### Timepoint

30 minute and 60 minute after analgesic injection

#### Method of measurement

visual analogue pain scale

## Secondary outcomes

empty

## Intervention groups

1

### Description

intervention: acetaminophen 15mg/kg Max 1000 mg every 6 hours IV for first day and morphine 0.1 mg/kg every 6 hours IV for second day

### Category

Treatment - Drugs

2

### Description

intervention: morphine 0.1 mg/kg every 6 hours IV for first day and acetaminophen 15 mg/kg Max 1000mg every 6 hours IV for second day

### Category

Treatment - Drugs

3

### Description

control: morphine 0.1 mg/kg every 6 hours IV for first day and second day

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Motahari Hospital

#### Full name of responsible person

Sohrabi Karim MD

#### Street address

yasemi ave. vali-asr ave. tehran.iran

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

tehran university of medical sciences

#### Full name of responsible person

research committee

#### Street address

Crossroad of Hemmat AND Fazl-allah Expway

#### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

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

Sohrabi Karim MD

#### Position

Emergency Medicine Resident

#### Other areas of specialty/work

#### Street address

Tehran

#### City

Tehran

#### Postal code

#### Phone

+98 21 4433 4806

#### Fax

#### Email

sohrabi@alborz.mui.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Salehi Reza MD

#### Position

assistant professor of anesthesiology department

#### Other areas of specialty/work

#### Street address

motahari hospital Tehran University of Medical Sciences

#### City

Tehran

#### Postal code

#### Phone

+98 21 6652 5327

#### Fax

#### Email

hbgssl@yahoo.com

**Web page address**

----

**Person responsible for updating data**

**Email**

sohrabi@alborz.mui.ac.ir

**Web page address**

----

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Sohrabi Karim MD

**Position**

Emergency Medicine Resident

**Other areas of specialty/work**

**Street address**

Emergency department rasul- akram hospital Tehran

University of Medical Sciences

**City**

Tehran

**Postal code**

Iran

**Phone**

+98 21 6652 5327

**Fax**

**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*