Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

EFFICACY OF INTRAVENOUS LIGNOCAINE AS ADJUVANT ANALGESIA IN BURN PATIENTS DURING CHANGE OF DRESSING UNDER GENERAL ANESTHESIA

Protocol summary

Study aim

The aim of this study is to compare the analgesic efficacy when intravenous lignocaine is used as adjuvant analgesia in burn patients during change of dressing under general anesthesia

Design

Two arm single blinded parallel group randomized controlled trial

Settings and conduct

This randomized controlled trial was carried out at the Department of Anesthesiology, Combined Military Hospital from Jan-Jun 2023. Participants were single blinded by using non-descript marked burettes one containing ligonicaine and one containing normal saline (placebo) prepared before the start of surgery. patients were not told about the preparation details.

Participants/Inclusion and exclusion criteria

Inclusion criteria included all ASA status patients presenting to the operating room for change of dressing under general anesthesia for full thickness burns (extending all dermal layers including bone, tissues, and ligaments). Exclusion criteria included patients with metastatic disease, major cardiac or respiratory disease, low ejection fraction, post chemotherapy, pregnant females, patients with partial thickness burns and unwilling to be included in the study

Intervention groups

The patients were divided into two groups after randomization in Group L (n=45) as the intravenous lignocaine group and Group A (n=45) as the non-adjuvant group without intravenous lignocaine.

Main outcome variables

Primary variables measured were mean heart rate, systolic and diastolic blood pressure, and oxygen saturation 5 minutes post-intubation and 15 minutes into the procedure and median pain scores 1-hour post-extubation in the recovery on standardized Visual Analog Scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230816059169N1**
Registration date: **2023-09-11, 1402/06/20**
Registration timing: **retrospective**

Last update: **2023-09-11, 1402/06/20**
Update count: **0**

Registration date

2023-09-11, 1402/06/20

Registrant information

Name

Muhammad Zaheer Ud din

Name of organization / entity

College of physcian and surgeons Pakistan

Country

Pakistan

Phone

+92 333 4319191

Email address

xaheertiwana@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-01, 1401/10/11

Expected recruitment end date

2023-06-30, 1402/04/09

Actual recruitment start date

2023-01-01, 1401/10/11

Actual recruitment end date

2023-06-30, 1402/04/09

Trial completion date

2023-06-30, 1402/04/09

Scientific title

EFFICACY OF INTRAVENOUS LIGNOCAINE AS ADJUVANT ANALGESIA IN BURN PATIENTS DURING CHANGE OF DRESSING UNDER GENERAL ANESTHESIA

Public title

LIGNOCAINE AS ANALGESIA IN BURN PATIENTS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All ASA status patients presenting to the operating room for change of dressing under general anesthesia for full thickness burns

Exclusion criteria:

Patient with metastatic disease, post chemotherapy Major cardiac or respiratory disease Patients with partial thickness burns Those unwilling to be included in the study

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were divided into two groups after randomization in Group L (n=45) as the intravenous lignocaine group and Group A (n=45) as the non-adjuvant group without intravenous lignocaine. The method of randomization was non-probability consecutive sampling via lottery method. All the patients were thoroughly counselled regarding the procedure and in case the patients were unable to communicate, permission was taken from the next of kin. An informed written high-risk consent was taken for surgery.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants in the study were briefed about the study protocol or how the results would be analyzed. 100 ml burettes containing the pre-mixed drug dose of lignocaine and one containing only normal saline were used to prevent observer bias.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ERB Combined Military Hospital Rawalpindi (CMH RWP)

Street address

CMH RWP

City

Rawalpindi

Postal code

46000

Approval date

2022-12-20, 1401/09/29

Ethics committee reference number

447

Health conditions studied

1

Description of health condition studied

Burns

ICD-10 code

T30.0

ICD-10 code description

Burn of unspecified body region, unspecified degree

Primary outcomes

1

Description

Mean heart rate, blood pressure and oxygen saturation

Timepoint

Pre-induction, 5 min and 30 minutes into procedure

Method of measurement

Standard cardiac monitor

2

Description

Median pain scores on standardized Visual Analog Scale

Timepoint

1-hour post-extubation in the recovery

Method of measurement

Standard Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group L (Intravenous lignocaine) Patients in Group L received intravenous lignocaine at a dose of 1.5 mg/kg infused over 5 minutes before induction whereas patient in Group A only received intravenous paracetamol and nalbuphine. Anesthesia was induced with intravenous propofol at 1.5 mg/kg, paralysis was achieved with atracurium 0.5 mg/kg and anesthesia was maintained with inhalational isoflurane at 1 MAC (minimum alveolar concentration)

Category
Treatment - Drugs

2

Description
Control group: Group A (Normal saline group) is the non-adjuvant group without intravenous lignocaine

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
CMH RWP

Full name of responsible person
Dr Muhammad Zaheer ud din

Street address
CMH RWP

City
Rawalpindi

Postal code
46000

Phone
+92 333 4319191

Email
xaheertiwana@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
CMH Rawalpindi

Full name of responsible person
Dr Muhammad Zaheer ud din

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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
CMH Rawalpindi

Proportion provided by this source
1

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
CMH Rawalpindi

Full name of responsible person
Dr Muhammad Zaheer ud din

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data collected included the Primary variables ie heart rate, systolic and diastolic blood pressure, and oxygen saturation 5 minutes post-intubation and 15 minutes into the procedure and median pain scores 1-hour post-extubation in the recovery on standardized Visual Analog Scale

When the data will become available and for how long

After approval from the primary author

To whom data/document is available

Public

Under which criteria data/document could be used

Study purpose

From where data/document is obtainable

the data would be available via email after contacting primary author ,email address is xaheertiwana@gmail.com

What processes are involved for a request to access data/document

An email would be sent to the primary author for data sharing request and once approved a link would be given to download the data.All this process would require around 7 days

Comments

This study needs furher research on a large scale