

Evaluation of the use of the local anaesthetic drug lidocaine to decrease pain and opioid doses in burned patient when given as intravenous infusion

Submission date 19/11/2017	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 08/01/2018	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 08/01/2018	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Treating of background pain in burned patients is difficult and requires high doses of opioids (pain relief medications) which often results in unfavorable symptoms and sometimes a life threatening complications such as respiratory depression. Intravenous administration (inserting liquids directly into a vein) of lidocaine (a type of opioid) showed a good effect in treating pain in burns. It has a peripheral and central effect on pain receptors with a significant decrease in release of prostaglandin E for burns in vivo, which is considered one of the most important mediators for peripheral pain. The aim of this study is to compare the opioids sparing effect among patients who received lidocaine IV infusion with that of those who received a placebo (normal saline).

Who can participate?

Adults aged 18 to 70 with burns that are more than 10 percent of their total body surface area .

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive the interventional drug of lidocaine intravenously through a vein, this is continued for seven days. Those in the second group receive normal saline for seven days.

What are the possible benefits and risks of participating?

The patients who were given lidocaine can benefit from the decreased pain killer doses. Adverse effects were meticulously monitored and dealt with immediately. Participants are followed up to measure their opioid consumption and pain levels at baseline, days 1-3 and days 4-6.

Where is the study run from?

Linköping Burn Center (Sweden)

When is the study starting and how long is it expected to run for?
Jan 2003 to April 2017

Who is funding the study?
Linköping University (Sweden)

Who is the main contact?
Professor Folke Sjöberg
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
Xylocard 001

Study information

Scientific Title
Effect of intravenous infusion of Xylocard on morphine consumption among patients with burns
> 10% TBSA

Study objectives
Intravenous infusion of lidocaine will result in decreased opioid consumption in burned patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Linköping Ethical Review Board, 2003/03/11, ref. (03-073)

Primary study design

Interventional

Study design

Single-centre double-blinded three block randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pain in burned patients

Interventions

Participants are randomly allocated to one of two groups: the intervention group or the control group.

Interventional drug: intravenous infusion of lidocaine starting with bolus dose 1 mg/kg, followed by lidocaine infusion 60 ml/hour for four hours 4mg/ml, then continuous infusion 45 ml/hour 4mg/ml for seven days.

Control Group: Equivalent volume of 0.9% Sodium Chloride starting with bolus dose, followed by lidocaine infusion 60 ml/hour for four hours, then continuous infusion 45 ml/hour for seven days.

Participants are followed up to measure their opioid consumption and pain levels at baseline, days 1-3 and days 4-6.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Xylocard : lidocaine, AstraZeneca

Primary outcome(s)

Opioid consumption (intravenous and oral in milligram/day) is measured using the recordings from both infusion pump and nurses' written doses administered at baseline day 0, days 1-3 and days 4-6.

Key secondary outcome(s)

Pain is measured using the visual analogue scale (measured six times per day) at baseline day 0, days 1-3 and days 4-6.

Completion date

04/10/2017

Eligibility

Key inclusion criteria

1. Burns more than 10 Total body surface area (tbsa)
2. Aged between 18 and 70 years
3. Administration of patient controlled analgesia (morphine)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Untreated AV-block type II or III
2. Known heart failure
3. Known allergy to local anaesthesia
4. Liver cirrhosis and severe renal dysfunction

Date of first enrolment

11/07/2005

Date of final enrolment

10/09/2014

Locations**Countries of recruitment**

Sweden

Study participating centre

Linköping Burn Center

Linköping University Hospital

Linköping

Sweden

58185

Sponsor information

Organisation

Linköping University

ROR

<https://ror.org/05ynxx418>

Funder(s)**Funder type**

University/education

Funder Name

Linköpings Universitet

Alternative Name(s)

Linköping University, Linköping University, LiU

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Results and Publications**Individual participant data (IPD) sharing plan**

The participant level data consists of anonymous numbers in a data sheet, which is stored within the data security system of the hospital where the researchers are working. There is no web link available as the security system does not allow external visitors. The process for requesting access can be initiated by the use of the contact details below.

Consent from participants was obtained for publication of the analysed results of the study. No consent was obtained for distributing individual data to external interests.

IPD sharing plan summary

Stored in repository