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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

Registration date
08/01/2018

Overall study status
Completed

Last Edited
08/01/2018

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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?
Linkoping 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?
Linkoping University (Sweden)

Who is the main contact?
Professor Folke Sjoberg
folke.sjoberg@liu.se

Contact information

Type(s)
Public

Contact name
Prof Folke Sjoberg

ORCID ID
http://orcid.org/0000-0002-5903-2918

Contact details
Burn Centre
University Hospital in Linkoping
Linkoping
Sweden
58185
+46 (0)101 031820
folke.sjoberg@liu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 lidocain will results 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)

Study design
Single-centre double-blinded three block randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

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

Overall study start date
18/01/2003

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. Adminstration of patient controlled anaglesia (morphine)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

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
Linkoping Burn Center
Linkoping University Hospital
Linkoping
Sweden
58185

Sponsor information

Organisation
Linkoping University

Sponsor details
Garnsionsgatan
Linkoping
Sweden
58185
+46 (0)101 030 000
liu@liu.se

Sponsor type
University/education

Website
www.liu.se

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
10/01/2018

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