ISRCTN90985804 https://doi.org/10.1186/ISRCTN90985804

S-ketamine to reduce negative pressure wound therapy dressing change associated pain

Submission date 01/12/2013	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/12/2013	**Overall study status** Stopped	
Last Edited 11/07/2022	**Condition category** Signs and Symptoms	

Plain English Summary

Background and study aims

We are carrying out a study on patients undergoing negative pressure wound therapy dressing changes. Common analgesics (painkillers) such as local anesthesia with lidocaine alone are often not effective for this procedure. Opioids are the most effective analgesics but their use is limited by numerous side effects, such as nausea, vomiting, constipation, urinary retention, dysphoria (an emotional state characterized by anxiety, depression or unease), euphoria (a feeling or state of intense excitement and happiness), altered cognitive (mental) function and hypoventilation (slow breathing). Other sedatives used for procedural sedation such as propofol or benzodiazepines offer no analgesia (pain relief) and may cause hypoventilation, alterations in hemodynamics and drowsiness. Ketamine is an old anaesthetic agent that also has analgesic properties. Ketamine also reduces the need for opioids and thus helps to reduce side effects caused by opioid medication.

Who can participate?

Adult patients aged over 18 undergoing elective wound dressing changes in the plastic surgery unit. 23 patients will be enrolled in the study.

What does the study involve?

The wound dressing changes will take place every 3-4 days for each patient. Each patient will be randomly allocated to receive either S-ketamine or saline on their first procedure and then on the second procedure the patient will be given the remaining medicine. Each patient will be given midazolam as a premedication before the procedure and a solution containing lidocaine with saline. If the pain is too great during the procedure, the patient will be given fentanyl as a rescue medication.

What are the possible benefits and risks of participating?

The possible benefits of participating in the study are improved analgesia during the procedure, reduced need for rescue medication (fentanyl) and fewer side effects caused by opioid medication. Possible risks are the side effects caused by ketamine. The most common side effect of ketamine is altered mental state. However, that can be prevented by giving midazolam as a premedication.

Where is the study run from?
The study is run from the Helsinki University Central Hospital Töölö Hospital, Finland.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment for the study will start in April 2014. Participants will be enrolled on the study for a period of one year, recruiting the last patient on April 2015. However, the recruitment period will be extended if necessary until 23 patients are enrolled.

Who is funding the study?
Helsinki University Central Hospital, Finland.

Who is the main contact?
Dr Vesa Kontinen
Dr Elina Brinck

Contact information

Type(s)
Scientific

Contact name
Dr Elina Brinck

Contact details
Helsinki University Central Hospital
Töölö Hospital
Topeliuksenkatu 5
PB 266
Helsinki
Finland
00029

Additional identifiers

EudraCT/CTIS number
2013-005114-35

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
S-ketamine to reduce negative pressure wound therapy dressing change associated pain: a prospective, randomized, blinded cross-over study

Acronym
KETAPLAST

Study hypothesis
S-ketamine effectively alleviates procedural pain and reduces the need for rescue medication (fentanyl) during negative pressure wound therapy dressing change compared to local anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Operative ethics committee of the Helsinki University Central Hospital, 12t/02/2014, ref: 38/13 /03/02/2014

Study design
Prospective randomized blinded cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Condition
Procedural pain related to negative pressure wound therapy dressing changes

Interventions
1. Intervention group: S-ketamine dose 0.25 mg/kg will be administered during negative pressure wound therapy dressing change in addition to local anaesthesia
2. Control group: placebo (saline)

The wound dressing changes will take place every 3-4 days for each patient. Each patient will be randomized to receive either S-ketamine or saline on their first procedure and then on the second procedure, she or he will be given the remaining medicine. Each patient will be given midazolam as a premedication before the procedure and a solution containing Lidocaine 1% with saline will be absorbed into the tissue treated. If the pain score (NRS scale) exceeds 5 during the procedure, she or he will be given fentanyl 0.5-1 ug/kg as a rescue medication.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
S-ketamine

Primary outcome measure
1. Pain measured using the NRS scale during the procedure, at the end of the procedure, and at three months after the procedure
2. Possible need for rescue medicine (fentanyl) during the procedure and, if needed, how much

Secondary outcome measures
To evaluate and compare the possible side effects such as altered mental state, desaturation, changes in blood pressure and heart rate associated with the treatment of S-ketamine or rescue medication (fentanyl):
1. Confusion measured with Richmond Agitation Sedation Scale (RASS) at 30 minutes and 60 minutes after the drug investigated (S-ketamine or placebo) has been given
2. Saturation with pulse oximetry (SpO2 %) at 15 minutes, 30 minutes and 60 minutes after the drug investigated (S-ketamine or placebo) has been given
3. Hemodynamic parameters (blood pressure mmHg and pulse beats/minute) at 15 minutes, 30 minutes and 60 minutes after the drug investigated (S-ketamine or placebo) has been given

Overall study start date
01/04/2014

Overall study end date
30/06/2021

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Participant inclusion criteria
Adult patients over 18 years undergoing elective negative pressure wound therapy wound dressing changes in the plastic surgery unit

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
23

Participant exclusion criteria
1. Body mass index over 35
2. Unstable ischaemic cardiac disease
3. Increased intracranial pressure
4. Increased intraocular pressure
5. Gravidity
6. Lactation
7. Hypersensitivity or allergy to ketamine, fentanyl or midazolam
8. Severe psychiatric disease
9. Inability to use the Numerical Rating Scale (NRS) pain scale

Recruitment start date
01/04/2014

Recruitment end date
31/12/2020

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Central Hospital
Helsinki
Finland
00029

Sponsor information

Organisation
Helsinki University Central Hospital (Finland)

Sponsor details
c/o Vesa Kontinen
Jorvi Hospital
Turuntie 150
PB 800
Helsinki
Finland
00029

Sponsor type
Hospital/treatment centre

Website
http://www.hus.fi/en/Pages/default.aspx

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Central Hospital (Finland)

Results and Publications

Publication and dissemination plan
This clinical trial will be a part of a doctoral thesis (In Finland, 3-5 trials are required for PhD in Medicine). Plans to publish the results of in a high-impact peer reviewed journal during 2018-2019.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from elina.brinck@hus.fi

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		19/01/2016	19/01/2017	No	Yes