

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

<b>Submission date</b> 01/12/2013	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/12/2013	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/07/2022	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### 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 objectives**

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

**Health condition(s) or problem(s) studied**

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

**Completion date**

30/06/2021

**Reason abandoned (if study stopped)**

Lack of staff/facilities/resources

**Eligibility****Key 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

**Key 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

**Date of first enrolment**

01/04/2014

**Date of final enrolment**

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](mailto:elina.brinck@hus.fi)

**IPD sharing plan summary**

Available on request

**Study outputs****Output type**

[Participant information sheet](#)

**Details****Date created**

19/01/2016

**Date added**

19/01/2017

**Peer reviewed?**

No

**Patient-facing?**

Yes