

# A randomised double-blind controlled trial of s-ketamine versus placebo in conjunction with best pain management in neuropathic pain in cancer patients

<b>Submission date</b> 12/04/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/study-anaesthetic-treat-cancer-related-nerve-pain>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Marie Fallon

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

NCT01316744

**Secondary identifying numbers**

KPS 2006-001

## **Study information**

**Scientific Title**

A randomised double-blind controlled trial of s-ketamine versus placebo in conjunction with best pain management in neuropathic pain in cancer patients

**Acronym**

KPS (Ketamine in Pain Study)

**Study objectives**

To establish whether s-ketamine given in addition to best standard pain management improves malignant neuropathic pain compared to best standard pain management alone. This is assessed using the sensory component of the McGill Short Form Questionnaire.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

West of Scotland Research Ethics Committee (1), 02/07/2008, ref: 08/S0703/103

**Study design**

Randomised double-blind trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Neuropathic pain in cancer patients

**Interventions**

Following a run-in period where opioid analgesia dose will be optimised (duration: 2 to 10 days), s-ketamine or placebo will be administered orally four times a day. The dose will be increased as per the titration schedule and dose increments will cease when pain or toxicity allow (duration 2 to 14 days until study medication titrated to maximum effect without side effects).

Assessment period - once study medication is completed patient enters 4 x four day assessment period to collect outcome data.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

S-ketamine

## **Primary outcome measure**

To establish whether s-ketamine given in addition to best standard pain management improves malignant neuropathic pain compared to best standard pain management alone. This is assessed using the sensory component of the McGill Short Form Questionnaire.

Timepoint: from the end of the run in period (prior to randomisation) at any one of the assessment time points (day 0 - end of titration period), day 4, day 8, day 12, day 16.

## **Secondary outcome measures**

1. To compare initial treatment benefit (at day 4 of assessment period of 16 days) using the sensory component of the McGill Short Form Questionnaire (timepoint : day 4 of assessment period of 16 days)
2. To compare difference in overall pain between the study arms based on the pain intensity (VAS score) (timepoint : daily throughout run in, titration and assessment period)
3. To compare difference in neuropathic pain between the study arms based on the LANSS pain scale
4. To compare patient distress between the two arms based on National Comprehensive Cancer Network (NCCN) Distress Thermometer (timepoint: end of run in period (prior to randomisation) and day 0, 4, 8, 12 and 16 of assessment period)
5. To assess the side-effects and tolerability of trial drug
6. To assess the effect of intervention on quality of life scores (based on Euroqol thermometer), anxiety and depression (based on Hospital Anxiety and Depression Scale [HADS]) and opioid requirements (timepoint: prior to randomisation, day 0, 4, 8, 12 and 16 of assessment period)

## **Overall study start date**

01/06/2007

## **Completion date**

29/04/2014

## **Eligibility**

### **Key inclusion criteria**

1. Aged greater than or equal to 18 years of age
2. Written informed consent
3. Neuropathic pain (as defined by the Leeds Assessment of Neuropathic Symptoms and Signs [LANSS]) that is related to underlying malignant disease
4. Neuropathic Pain greater than or equal to four on a zero to ten (Visual Analogue Scale [VAS]) and a McGill Sensory Scale Score greater than five
5. Will have had a trial of an adjuvant analgesic (gabapentin or amitriptyline)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

214

**Total final enrolment**

214

**Key exclusion criteria**

1. Planned to receive chemotherapy or radiotherapy which may change pain during the period of the study
2. Diastolic Blood Pressure greater than 100 mmHg
3. History of seizures in last two years
4. Class I anti-arrhythmic drugs
5. Life expectancy less than two months
6. Patients who are actively hallucinating

**Date of first enrolment**

24/04/2009

**Date of final enrolment**

29/04/2014

**Locations****Countries of recruitment**

United Kingdom

**Study participating centre**

Edinburgh Cancer Centre  
Edinburgh

United Kingdom  
EH4 2 XU

## Sponsor information

### Organisation

Greater Glasgow and Clyde Health Board/Glasgow University (UK)

### Sponsor details

NHS North Glasgow University Hospitals Division  
West R & D Office, Administration Building  
Ground Floor, Room 9  
Western Infirmary  
Glasgow  
Scotland  
United Kingdom  
G11 6NT

### Sponsor type

Hospital/treatment centre

### Website

<http://www.nhs.uk/content/>

### ROR

<https://ror.org/05kdz4d87>

## Funder(s)

### Funder type

Charity

### Funder Name

Cancer Research UK

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2018	18/02/2019	Yes	No
<a href="#">Plain English results</a>			25/10/2022	No	Yes