

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

Submission date 12/04/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 27/04/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/10/2022	Condition category Cancer	☐ 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

Palliative Medicine/Oncology
Edinburgh Cancer Centre
University of Edinburgh
Western General Hospital
Crewe Road
Edinburgh
United Kingdom
EH4 2 XU

Additional identifiers

ClinicalTrials.gov (NCT)

NCT01316744

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double-blind trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary**Study outputs**

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