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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	[X] Prospectively registered [_] Protocol
Registration date 27/04/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] 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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01316744

Protocol serial number

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

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