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Investigation of the Potentiation of the Analgesic Effects of Fentanyl by Ketamine in Humans: a Double-blinded, Randomised, Placebo Controlled, Crossover Study of Experimental Pain

Submission date 10/04/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/04/2005	**Overall study status** Completed	
Last Edited 07/01/2021	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MMC

Study information

Scientific Title
Investigation of the Potentiation of the Analgesic Effects of Fentanyl by Ketamine in Humans: a Double-blinded, Randomised, Placebo Controlled, Crossover Study of Experimental Pain

Study objectives
The current investigation explored the interaction between ketamine and the opioid fentanyl in the anticipation that a low dose of ketamine might potentiate the analgesic effect of fentanyl. Furthermore, it was hypothesised that the interaction of these drugs might be associated with selective potentiation of analgesia without associated increased sedation; that is that potentiation might occur in the context of a very low dose of ketamine that was not otherwise associated with brain effects such as sedation. It was hoped that the identification of such doses of ketamine may enable better future management of both opioid sensitive physiological pain and NMDA receptor-mediated sensitisation without the disadvantage of increased sedation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
The ten volunteers each attended five three-hour laboratory sessions on separate occasions. In each session, the volunteer received one of the following treatments:

Placebo (saline)
Propofol
Ketamine
Fentanyl
Ketamine and Fentanyl

Therefore, each volunteer was exposed to each of the five treatments, over five sessions, with the order of treatment randomised for each volunteer. During each session, the test battery was performed prior to drug administration as a measure of baseline and then repeated when the target concentrations were reached.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ketamine, propofol, fentanyl

Primary outcome measure
Pain threshold to electrical current, pain threshold to contact heat, pain threshold to pressure, visual analogue scale for sedation, Observer Assessment of Alertness/Sedation Scale (OASS), Symbol Digit Modalities Test (SDMT), auditory reaction time

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2005

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Ten healthy male volunteers were recruited via bulletin board advertisements. The volunteers were trained in the test procedures employed and medically screened.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants

10

Total final enrolment
10

Key exclusion criteria
Volunteers were excluded if they had a history of cardiac, neurological, or musculoskeletal disease. Other exclusion criteria included a history of drug abuse, pain syndromes, myasthenia gravis, acute narrow angle glaucoma, asthma, or heart failure, concurrent use of any analgesics, sedatives, erythromycin, monoamine oxidase (MAO) inhibitors, or allergy to propofol, fentanyl, or ketamine.

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Australia

Study participating centre
Dept Anaesthesia
Clayton
Australia
3168

Sponsor information

Organisation
Monash Medical Centre (Australia)

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Sponsor type
Not defined

ROR
https://ror.org/036s9kg65

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Monash Medical Centre

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/04/2005		Yes	No