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	
Registration date	Overall study status	ProtocolStatistical analysis plan	
_	Completed	[X] Results	
Last Edited 07/01/2021	Condition category Signs and Symptoms	[] Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

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)

Sponsor details

246 Clayton Road Clayton Australia 3168 +61 3 95946666 adam.tucker@med.monash.edu.au

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