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Effects of NMDA-receptor antagonism on hyperalgesia, opioid use, and pain after major surgery in young and elderly patients

Submission date 26/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/09/2005	**Overall study status** Completed	
Last Edited 11/12/2007	**Condition category** Surgery	

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

MCT-52682

Study information

Scientific Title

Study objectives
Our primary aim is to determine whether perioperative NMDA-receptor antagonism has differential effects on postoperative pain, hyperalgesia and morbidity in younger and older patients. In order to achieve this aim, we propose to conduct the first randomized, double-blind placebo-controlled study designed to investigate age differences in the effects of perioperative oral administration of an NMDA-receptor antagonist (amantadine) in men undergoing radical prostatectomy. In addition, age differences in psychosocial factors and the pharmacological properties of amantadine and morphine will be measured to control for, and clarify, their contribution to the differences found.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the University Health Network Research Ethics Board, Toronto, Ontario on the 12th November 2003.

Study design
Randomised controlled 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
Postoperative pain in radical prostatectomy

Interventions
Amantadine versus Placebo comparison.

Trial details received: 12 September 2005

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amantadine

Primary outcome measure
Hyperalgesia and opioid consumption.

Secondary outcome measures
Assess age differences in the intensity and course of secondary hyperalgesia after surgery.

Overall study start date
01/04/2002

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Able to read and write English
2. Age 18 - 54 years or greater than 55 years, male
3. American Society of Anesthesiologists (ASA) class 1 to 3
4. Scheduled for elective radical prostatectomy
5. Body weight between 60 and 90 kg, Body Mass Index (BMI) less than or equal to 30

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
132

Key exclusion criteria
1. Significant Central Nervous System (CNS), respiratory, cardiac, hepatic, renal or endocrine dysfunction and/or any significant sequelae
2. Contraindications allergies to, and/or past adverse reactions to opioid analgesics or amantadine
3. History of Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) axis I

disorder or cognitive dysfunction
4. History of epilepsy or other seizures
5. History of chronic pain of at least 6 months duration
6. History of long-term opioid use for chronic pain
7. History of long-term use of amantadine or other antiparkinsonian drug
8. Ingestion of antiussive medication within 48 hours before surgery
9. History of alcohol or drug dependency/abuse of at least 6 months duration

Date of first enrolment
01/04/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Canada

Study participating centre
Department of Anaesthesia
Toronto
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Sponsor information

Organisation
University Health Network, Toronto (Canada)

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Sponsor type
University/education

Website
http://www.uhnresearch.ca

ROR
https://ror.org/026pg9j08

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-52682)

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