

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/12/2007	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

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 antiemetic 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

Canada

M5G 2C4

Sponsor information

Organisation

University Health Network, Toronto (Canada)

Sponsor details

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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