

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
Registration date 26/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 11/12/2007	Condition category Surgery	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lucia Gagliese

Contact details
Department of Anaesthesia
Toronto General Hospital
200 Elizabeth Street
Toronto
Canada
M5G 2C4
+1 416 340 4296
lucia.gagliese@uhn.on.ca

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

Hyperalgesia and opioid consumption.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration