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

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

**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.

## Primary study design
Interventional

## Study design
Randomised controlled trial

## 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 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
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