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Post-operative Haloperidol versus Placebo for prevention of post-operative delirium after acute hip surgery

Submission date	Recruitment status	[ ] Prospectively registered
06/11/2005	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/02/2006	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/02/2019	Injury, Occupational Diseases, Poisoning	[ ] 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
NCT00250237

Secondary identifying numbers
N/A

Study information

Scientific Title
Post-operative Haloperidol versus Placebo for prevention of post-operative delirium after acute hip surgery

Study objectives
In this study we want to determine if treatment with haloperidol directly after acute hip surgery in high risk patients protects against developing a post-operative delirium.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes, Medical Ethics Committee Southwest Holland (Medisch Ethische Toetsingscommissie [METC] Zuidwest Holland). Date of approval: September 2nd 2005.
METC number: 05-56.

Study design
Randomised double-blind placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hip fracture

Interventions
Post-operative Haloperidol versus Placebo

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Incidence of post-operative delirium

Secondary outcome measures
1. Mortality
2. Activities of daily living (ADL) dependency

Overall study start date
10/11/2005

Completion date
10/11/2007

Reason abandoned (if study stopped)
Lost randomisation key

Eligibility

Key inclusion criteria
1. Patients aged 75 years and older
2. Hip Fracture

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
206

Key exclusion criteria
1. Younger patients
2. Pre-operative delirium
3. Contra-indications for use of haloperidol

Date of first enrolment
10/11/2005

Date of final enrolment
10/11/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Bronovolaan 4
The Hague
Netherlands
2597 AX

Sponsor information

Organisation
Research Fund Bronovo Hospital (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03r781319

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Research Fund Bronovo Hospital

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2015 short research article in https://doi.org/10.9734/BJMMR/2015/17815 (added 01/02/2019)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration