ISRCTN16416351 https://doi.org/10.1186/ISRCTN16416351

The efficacy of levobupivacaine, ropivacaine and bupivacaine for combined psoas compartment - sciatic nerve block in patients undergoing total hip replacement

Submission date
27/06/2007

Recruitment status
No longer recruiting

Registration date
27/06/2007

Overall study status
Completed

Last Edited
28/10/2008

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Roberto S.G.M. Perez

Contact details
Vrije University Medical Centre
Department of Anaesthesiology
P.O. Box 7057
Amsterdam
Netherlands
1007 MB
+31 (0)20 444 0029
rsgm.perez@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR990

Study information

Scientific Title

Study objectives
Psoas compartment - sciatic nerve block, as an adjuvant locoregional anaesthetic technique, gives sufficient post operative pain reduction after total hip replacement, regardless which long acting local anaesthetic ([levo]bupivacaine or ropivacaine in equipotent dosages) is used.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, controlled, double blinded, parallel group trial

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
Psoas compartment block, sciatic nerve block, total hip replacement

Interventions
Psoas compartment - sciatic nerve block given with bupivacaine, levobupivacaine or ropivacaine.
Duration of the intervention: 10 minutes

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Bupivacaine, levobupivacaine, ropivacaine

Primary outcome measure
Pain (Visual Analog Scale) at T = 4, 8, 12, 24, 48 hours post-puncture.

Secondary outcome measures
1. Degree of motor block (Modified Bromage Scale) at T = 4, 8, 12, 24, 48 hour post-puncture
2. Degree of sensory block (loss of pin-prick sensation in leg dermatomes) at T = 4, 8, 12, 24, 48 hour post-puncture

Overall study start date
01/06/2003

Completion date
01/01/2005

Eligibility

Key inclusion criteria
1. Age above 18
2. American Society of Anaesthesiologists (ASA) classification I - III
3. Total Hip Replacement under general anaesthesia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
45

Key exclusion criteria
1. Coagulation disorders
2. Infections at puncture sites
3. Known allergy to local anaesthetics
4. Pre-existing neurological dysfunction
5. Not being able to properly communicate

Date of first enrolment
01/06/2003

Date of final enrolment
01/01/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije University Medical Centre
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
Department of Anesthesiology
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Vrije University Medical Centre (VUMC) (The Netherlands)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2008		Yes	No