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The effect of pregabalin on post-operative pain and recovery after kidney transplantation [Pregabaliinin vaikutus leikkauskipuun ja toipumiseen munuaisensiirtopotilailla]

Submission date
01/10/2010

Recruitment status
No longer recruiting

Registration date
20/10/2010

Overall study status
Completed

Last Edited
20/10/2010

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
KirKipu09-1

Study information

Scientific Title
The effect of pregabalin on post-operative pain and recovery after kidney transplantation: a double blind, randomised, active-placebo controlled parallel-group clinical trial

Study objectives
Premedication with pregabalin will reduce post-operative pain after kidney transplantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki University Central Hospital (Helsingin ja Uudenmaan sairaanhoitopiiri) Ethics Committee approved on the 14th October 2009

Study design
Double blind randomised active-placebo controlled parallel-group phase IV clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Postoperative pain

Interventions
Treatment arm: single dose of pregabalin (150 mg if body weight 40 - 80 kg and 300 mg if body weight 80 - 120 kg) orally as premedication 1 hour before entering operating suite.

Control arm: single dose of diazepam (7.5 mg if body weight 40 - 80 kg and 15 mg if body weight 80 - 120 kg) orally as premedication 1 hour before entering operating suite.

Follow-up 14 days after the operation in both arms.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome measure
PCA opioid (oxycodone) consumption 24 after the operation

Secondary outcome measures
1. Patient-reported pain in rest and movement, type of movement provoking pain, dizziness, tiredness, nausea and vomiting, bladder irritation, bowel movements, self-reported overall ability and mood, measured every 12 hours from the first post-operative day to 14 days after the operation
2. Assessment of sedation and anxitety when entering operating suite (1 hour after drug administration)
3. Assessment of pain, bladder irritation, nausea and vomiting, dizziness and sedation and patient-reported symptoms measured at 15, 30, 45, 60, 75, 90, 105, 120, 150, 180, 240 minutes and 6 and 8 hours after the end of the operation
4. Bowel function and kidney function
5. Blood sample for measurement of plasma pregabalin concentration taken at 2, 8, 16 and 24 hours after drug administration

Overall study start date
01/04/2010

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Patients receiving allogenic kidney transplant from a brain-dead donor volunteering to participate
2. Male and female, over 18 years, no study-related upper age limit (but very old persons are usually not accepted as recipients for a kidney transplant)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
140

Key exclusion criteria
1. Chronic opioid or gabapentinoid treatment
2. Unable to communicate in Finnish or Swedish language
3. Krooninen opioidilääkitys
4. Unable to use PCA
5. Unable to use NRS (numeral rating scale) for pain assessment
6. Allergy to pregabalin, oxycodone, propofol or remifentanil
7. Body weight less than 40 kg or greater than 120 kg

Date of first enrolment
01/04/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki University Central Hospital
Helsinki
Finland
FI-00029 HUS

Sponsor information

Organisation
Helsinki University Central Hospital (Finland)

Sponsor details
Pain Research Group
Unit of Surgery, Section of Anaesthesiology
P.O.Box 263
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FI-00029 HUS

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/02e8hzf44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Helsinki University Central Hospital (Finland) - research funds

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