

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/10/2010	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

PCA opioid (oxycodone) consumption 24 after the operation

Key secondary outcome(s))

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 anxiety 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 remifentanyl

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)

ROR

<https://ror.org/02e8hzf44>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Helsinki University Central Hospital (Finland) - research funds

Results and Publications

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?
	Participant information sheet				

