ISRCTN46781597 https://doi.org/10.1186/ISRCTN46781597

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

**Submission date**
01/10/2010

**Registration date**
20/10/2010

**Last Edited**
20/10/2010

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**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

**Contact name**
Dr Vesa Kontinen

**Contact details**
Helsinki University Central Hospital
Unit of Surgery, Section of Anaesthesiology, Pain Relief
P.O.Box 263, FI-00029 HUS
Finland
Helsinki
Finland
FI-00029 HUS

## 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

## Primary study design
Interventional

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

## 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 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

### 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 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)

**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