

# Short versus long buprenorphine-naloxone treatment in intravenous buprenorphine withdrawal: a randomised controlled trial

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| <b>Submission date</b><br>17/09/2007   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>04/03/2008 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>04/03/2008       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <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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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HDL07-01

# Study information

## Scientific Title

## Acronym

BUNXLOW

## Study objectives

1. To investigate the effectiveness of buprenorphine-naloxone compared with treatment as usual (lofexidine) in withdrawal of intravenous buprenorphine dependence
2. To determine whether a longer regime is more effective than a shorter one

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from:

1. The Ethics Committee for Pediatrics, Adolescent Medicine and Psychiatry/Hospital District of Helsinki and Uusimaa on the 15th May 2007; amendment on the form of informed consent was approved 19th June 2007 (ref: 148/E7/2007)
2. The National Agency for Medicines approval on the 22nd August 2007 (ref: 96/2007)

## Study design

Randomised, active controlled, three-arm, parallel group, single centre trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Intravenous misuse of buprenorphine

## Interventions

1. Short buprenorphine-naloxone (Bu-nx) arm: for 9 days:
  - Day 1: 8 mg
  - Days 2 - 3: 8 - 16 mg (dose according to clinical assessment)
  - Days 4 - 5: 8 mg
  - Days 6 - 7: 4 mg
  - Days 8 - 9: 2 mg

2. Long buprenorphine-naloxone arm: for 25 days:

Day 1: 8 mg

Days 2 - 3: 8 - 16 mg (dose according to clinical assessment)

Days 4 - 9: 8 mg

Days 10 - 12: 6 mg

Days 13 - 16: 4 mg

Days 17 - 20: 2 mg

Days 21 - 25: 1 mg

3. Lofexidine arm: lofexidine according to clinical assessment, maximum dose 2.4 mg/d divided into two to three doses, maximum duration 21 days

In all arms, the intended withdrawal duration (in-patient treatment) is 28 +/- 7 days, and the follow-up period is up to six months after that.

## **Intervention Type**

Drug

## **Phase**

Not Specified

## **Drug/device/biological/vaccine name(s)**

Buprenorphine-naloxone, lofexidine

## **Primary outcome measure**

1. Completion of withdrawal
2. Retention in rehabilitation for one month
3. Abstinence at one month after withdrawal
4. Abstinence at six months after withdrawal

## **Secondary outcome measures**

1. The extent of withdrawal symptoms experienced, recorded every day during withdrawal
2. The amount of additional medication needed, recorded every day during withdrawal
3. Whether the patient begins naltrexone medication, patients will be offered an opportunity to begin naltrexone three days before finishing withdrawal
4. Patient satisfaction, measured at the last day of withdrawal, whether at the intended finishing date, or at premature termination of withdrawal. Satisfaction will be measured by a self-made questionnaire of seven questions concerning the satisfaction with the medication, the length of medication, the additional medication, the length of withdrawal, the staff, the opportunity of beginning naltrexone and the overall satisfaction with the withdrawal treatment. Answers will be recorded with a five-grade scale

## **Overall study start date**

24/09/2007

## **Completion date**

31/12/2008

## **Eligibility**

**Key inclusion criteria**

1. Opiate dependence (Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition [DSM IV])
2. Current misuse of buprenorphine intravenously (minimum 3 mg/day) (use confirmed by urinalysis)
3. Willingness to participate in withdrawal in the treatment centre and in rehabilitation afterwards
4. Aged between 18 and 50

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

50 Years

**Sex**

Both

**Target number of participants**

120 patients

**Key exclusion criteria**

1. Other than buprenorphine as the primary drug of misuse
2. Misuse of other opiates than buprenorphine during the last week (confirmed by urinalysis)
3. Opiate maintenance therapy
4. Psychotic symptoms at recruitment
5. Psychiatric or somatic disease or symptoms that may require hospitalisation at near future
6. Salient increase in alanine aminotransferase (ALAT)
7. Pregnancy
8. Allergy to lofexidine, buprenorphine or naloxone
9. Former participation to the same study
10. Concurrent participation to other intervention studies
11. Native language other than Finnish

**Date of first enrolment**

24/09/2007

**Date of final enrolment**

31/12/2008

**Locations****Countries of recruitment**

Finland

**Study participating centre**  
**Munkkisaarencatu 16**  
Helsinki  
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01500

## **Sponsor information**

**Organisation**  
Helsinki Deaconess Institute (Finland)

**Sponsor details**  
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**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.hdl.fi>

**ROR**  
<https://ror.org/04zqw9t81>

## **Funder(s)**

**Funder type**  
Research organisation

**Funder Name**  
Academy of Finland (Finland)

**Alternative Name(s)**  
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

**Funding Body Type**  
Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Finland

**Funder Name**

National Public Health Institute (Finland)

**Funder Name**

Helsinki Deaconess Institute (Finland)

## **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