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

Submission date	Recruitment status	[ ] Prospectively registered
17/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/03/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/03/2008	Mental and Behavioural Disorders	[ ] 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
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, iofexidine

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 (mimimun 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 then 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
Munkkisaarenkatu 16
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Sponsor information

Organisation
Helsinki Deaconess Institute (Finland)

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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