

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

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

Protocol serial number

HDL07-01

Study information

Scientific Title

Acronym

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 (mimimum 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

All

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

Munkkisaarenkatu 16

Helsinki

Finland

01500

Sponsor information

Organisation

Helsinki Deaconess Institute (Finland)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Academy of Finland (Finland)

Alternative Name(s)

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Finland

Funder Name

National Public Health Institute (Finland)

Funder Name

Helsinki Deaconess Institute (Finland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary