ISRCTN14951861 https://doi.org/10.1186/ISRCTN14951861

Opiate detoxification study

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/04/2009	Mental and Behavioural Disorders	

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
N0120148502

Study information

Scientific Title

Study objectives
To investigate whether buprenorphine opiate detoxification regime can be considered to be at least as clinically effective as a lofexidine regime, which was taken at the reference treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Drug addiction

Interventions
The study was a randomised controlled trial (RCT) using a non-inferiority approach. Non-inferiority is demonstrated if, within a 95% confidence interval, buprenorphine performs within a preset tolerance limit of clinically acceptable differences in outcomes, completion rates between the two treatments.

Individual ready for heroin detoxification were given information about the trial and invited to participate. Consenting participants were then randomised to one of the two treatments. Detoxification was undertaken in a specialist outpatient clinic according to pre-defined protocols. The detoxification procedure required that this was an open label trial. The primary outcome was whether or not an individual completed the detoxification. Completion of the planned detoxification was taken to be an objective marker of both the acceptability of the pharmacotherapy and also the effectiveness of the detoxification procedure in the clinic. Abstinence at one-month follow-up was taken as an indicator of overall treatment effectiveness and was used as a secondary outcome measure.

The difference in completion proportions between the two treatments was then tested to determine whether or not the treatments could be considered clinically equivalent. Data were also collected for individuals who declined randomisation and instead chose their treatment. Additional secondary outcome measures were substance use, dependence, psychological health, social satisfaction and treatment satisfaction.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Buprenorphine, lofexidine

Primary outcome(s)
The primary outcome was whether or not an individual completed the detoxification.

Key secondary outcome(s))
Abstinence at one-month follow-up was taken as an indicator of overall treatment effectiveness and was used as a secondary outcome measure.

Completion date
30/09/2004

Eligibility

Key inclusion criteria
Individual ready for heroin detoxification who agreed to take part in the trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2000

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addictions Unit
Leeds
United Kingdom
LS2 9NG

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Leeds Mental Health Teaching NHS Trust (UK) NHS R&D Support Funding

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?
Results article	results	01/12/2005		Yes	No