

Opiate detoxification study

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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