ISRCTN07752728 https://doi.org/10.1186/ISRCTN07752728

The Leeds Evaluation of Efficacy of Detoxification Study (LEEDS project): a randomised controlled trial comparing the effects of differing therapeutic agents for detoxification from either street heroin or methadone

Submission date
29/05/2002

Recruitment status
No longer recruiting

Registration date
29/05/2002

Overall study status
Completed

Last Edited
05/01/2011

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] 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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United Kingdom
LS9 8AA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
None

Study information

Scientific Title

Acronym
LEEDS project

Study objectives
The Leeds Evaluation of Efficacy of Detoxification Study (LEEDS) project is a pragmatic randomised trial which will compare the open use of buprenorphine with dihydrocodeine for illicit opiate detoxification, in the UK primary care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval for the trial has been granted from the NHS Local Research Ethics Committee based at Saint James's University Hospital, Leeds.

Study design
Randomised controlled 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
Participants are taking street opiates or street methadone

Interventions
A randomised controlled trial will be implemented using buprenorphine sublingual tablets or dihydrocodenine. Prescriptions for either of the two therapeutic agents will be randomly

assigned to participants over a two week treatment programme. A urine sample will be taken on the day the final prescription is written to determine abstinence of opiates. Follow up studies will be conducted at three and six month stages where a brief questionnaire will be asked.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Abstinence from street opiates at receiving the final prescription, indicated by a urine test free of illicit opiates or their metabolites.

Secondary outcome measures
1. Significant adverse effects
2. Inappropriate use of prescribed medication (e.g. intentional overdose)
3. Presentation at Accident and Emergency Departments
4. Admission to hospital

Overall study start date
01/03/2002

Completion date
01/03/2005

Eligibility

Key inclusion criteria
1. Above the age of 18 years
2. Using moderate levels of street opiates or taking street methadone
3. Have expressed a wish to detoxify from either street heroin or methadone through a standard monitored process
4. Participants must be registered at one of the practices taking part in the LEEDS project

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
01/03/2002

Date of final enrolment
01/03/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NFA Health Centre for Homeless People
Leeds
United Kingdom
LS9 8AA

Sponsor information

Organisation
NFA Health Centre for Homeless People (UK)

Sponsor details
68 York Street
Leeds
England
United Kingdom
LS9 8AA

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name
North East Primary Care Trust (formerly Leeds Health Authority) (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol for open-label pragmatic randomised control trial	29/04/2004		Yes	No
Protocol article	protocol for pilot study of randomised controlled trial	08/01/2007		Yes	No
Results article	results	05/02/2009		Yes	No