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The Leeds Evaluation of Efficacy of Detoxification Study (LEEDS) Prisons Project: An open label pragmatic randomised controlled trial comparing the efficacy of differing therapeutic agents for prison primary care detoxification from illicit opiates

Submission date
16/08/2005

Recruitment status
No longer recruiting

Registration date
15/09/2005

Overall study status
Completed

Last Edited
24/01/2023

Condition category
Mental and Behavioural Disorders

[X] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3

Study information

Scientific Title
The Leeds Evaluation of Efficacy of Detoxification Study (LEEDS) Prisons Project: An open label pragmatic randomised controlled trial comparing the efficacy of differing therapeutic agents for prison primary care detoxification from illicit opiates

Acronym
LEEDS

Study objectives
To evaluate whether buprenorphine or methadone given openly to illicit opiate users presenting for detoxification in the UK NHS prison setting helps achieve abstinence at completion of regime

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

Secondary study design
Randomised controlled trial

Study setting(s)
Prison/detention

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Problematic use of illicit opiates requiring medical detoxification

Interventions
Buprenorphine or methadone

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Buprenorphine and methadone

Primary outcome measure
Abstinence of illicit opiates 5 days post completion of detoxification as indicated by a urine test

Secondary outcome measures
Adverse events recorded during the detoxification period: inappropriate use of prescribed medication, overdose, admission to prison healthcare, accident and emergency (A&E) or hospital. Abstinence at 1, 3 and 6 months post detoxification. At 1, 3 and 6 months: evidence and volume of service utilisation.

Overall study start date
01/11/2005

Completion date
01/11/2007

Eligibility

Key inclusion criteria
Male or female, 18-65 years old, using illicit opiates as confirmed by a urine test at first assessment, remaining in the prison estate for longer than 28 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
340

Key exclusion criteria

Contraindications to buprenorphine or methadone,
co-existing acute medical conditions requiring emergency admission to hospital so precluding detoxification in the prison setting, currently undergoing detoxification from other addictive drugs whereby concurrent detoxification from illicit opiates would not be clinically indicated, women who are pregnant or breastfeeding, prisoners previously randomised into this trial

Date of first enrolment
01/11/2005

Date of final enrolment
01/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept. of Psychiatry
Leeds
United Kingdom
LS2 9LT

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
School of Medicine
24 Hyde Terrace
Leeds
England
United Kingdom
LS2 9LN

Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Department of Health Forensic Mental Health Research Funding Scheme 2004 (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	14/07/2009		Yes	No
Results article	results	01/12/2011		Yes	No