

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	☒ Prospectively registered
		☒ Protocol
Registration date 15/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 24/01/2023	Condition category Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Clive Adams

Contact details

Dept. of Psychiatry
15 Hyde Terrace
Leeds
United Kingdom
LS2 9LT

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation
University of Leeds (UK)

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

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