

# 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

<b>Submission date</b> 16/08/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/09/2005	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 24/01/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## 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/024mrx33>

## 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?
<a href="#">Results article</a>	results	01/12/2011		Yes	No
<a href="#">Protocol article</a>	protocol	14/07/2009		Yes	No