

Injectable versus oral opioid maintenance treatment for heroin addicts currently failing to benefit from standard treatment: a three way Randomised Controlled Trial (RCT) of injectable heroin versus injectable methadone versus oral methadone maintenance

Submission date 14/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/09/2014	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

KCL/SLaM-CT2004-3

Study information

Scientific Title

Acronym

RIOTT (Randomised Injectable Opioid Treatment Trial)

Study objectives

The research objective of the trial is to examine the safety, efficacy and cost effectiveness of treatment with injectable methadone or injectable heroin compared to optimised oral methadone treatment, for patients not responding to their current oral maintenance treatment episode.

Hypotheses:

1. A selected group of patients (not responding to usual oral methadone treatment) receiving injectable heroin treatment or injectable methadone treatment, will make greater reductions in their illicit heroin use, other drug use and criminal activity and greater improvements in their health and social functioning, than if provided with optimised oral methadone treatment
2. Providing injectable heroin or injectable methadone to a selected group of patients (not responding to usual oral methadone treatment) results in a greater economic benefit per extra unit of resource invested in the treatment, than only offering optimised oral methadone

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Institute of Psychiatry Ethics Committee for single-site study, 26/02/2004, ref: 291/03
2. London MREC for multi-site study, 03/06/2006, ref: 06/MREC02/22

Study design

Multi-site open-label randomised controlled trial to compare the safety, efficacy and cost-effectiveness of prescribing injectable opiates versus optimised oral methadone

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**

Opiate dependence/addiction

Interventions

Patients randomised to receive optimised oral methadone treatment will receive methadone treatment under enhanced conditions. The intervention will include high methadone doses (at least 80 mg), supervised dispensing of medications contingent upon levels of unsanctioned drug use (daily supervised dosing initially), and patients will be expected to attend for regular key worker and medical appointments. Methadone is a semi-synthetic opioid used in the treatment of opioid drug dependence to prevent opioid withdrawal syndrome by substituting for heroin.

The injectable methadone group will receive treatment with once-daily injectable (intravenous [IV] /intramuscular [IM]) methadone ampoules. There will be full supervision of all injected doses. Patients will be expected to attend for regular key worker and medical appointments. Patients will be able to supplement their injectable methadone dose with prescribed oral methadone doses. Methadone Hydrochloride B.P. for injection is a colourless, preservative and oxidant free solution in clear glass ampoules.

Those receiving injectable heroin will receive treatment with injectable (IV/IM) heroin ampoules, administered under supervision up to twice a day. Patients will be expected to attend for regular key worker and medical appointments. Patients will be able to supplement their injectable heroin dose with prescribed oral methadone doses. Diacetylmorphine hydrochloride (Diamorphine hydrochloride, heroin hydrochloride, heroin) is a opioid used in the treatment of opioid drug dependence. All injections are supervised in the clinic.

All those receiving injectable treatment or optimised oral methadone treatment will receive named keyworker and frequent reviews and ancillary services. The total duration of treatment and follow-up is 6 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Heroin, methadone

Primary outcome measure

Reduction in illicit heroin, measured by urine drug screens taken on a weekly basis over 6 months.

Secondary outcome measures

Self-reported to researcher at baseline, 3 months and 6 months (in or out of treatment):

1. Changes in illicit heroin use:

1.1. Number of days used illicit heroin in past 30 days

- 1.2. No days injected/smoked/snorted illicit heroin in past 30 days
- 1.3. Average cost of illicit heroin on days used
- 1.4. Frequency of use in past month, as measured by the Drug Use Section of Opiate Treatment Index (OTI Q score)
2. Changes in other illicit opiate drug use (non-prescribed):
 - 2.1. Injectable opioid pharmaceuticals (methadone, heroin)
 - 2.1.1. Days used in past 30 days
 - 2.1.2. Average cost
 - 2.1.3. Estimate quantity on average day of use
 - 2.2. Oral methadone/morphine:
 - 2.2.1. Days used in past 30 days
 - 2.2.2. Average cost
 - 2.2.3. Estimate quantity on average day of use
 - 2.3. Codeine/codeine like preparations:
 - 2.3.1. Days used in past 30 days
 - 2.3.2. Average cost
 - 2.3.3. Estimate quantity on average day of use
3. Changes in illicit cocaine use:
 - 3.1. Number of days used crack/cocaine in past 30 days
 - 3.2. No days injected/smoked/snorted in past 30 days
 - 3.3. Average cost of cocaine on days used
4. Other illicit drug use and alcohol - benzodiazepines, alcohol, cannabis:
 - 4.1. No days used past 30 days
 - 4.2. Average quantities consumed (estimated as diazepam mg equivalents; units alcohol; grams cannabis)
 - 4.3. Average cost of each drug used on average day
5. Changes in high-risk injecting practices:
 - 5.1. Participation in risk practices for blood borne virus transmission in preceding month using the Injecting Risk Questionnaire, with responses pegged according to number of times occurred in the past month
 - 5.2. Assessment of injecting practices using self-report scale developed for the trial
6. Changes in general health status:
 - 6.1. 36-item Short Form health survey (SF-36)
 - 6.2. Euro-QoL instrument (EQ-5D)
7. Changes in psychosocial functioning:
 - 7.1. 36-item Short Form health survey (SF-36)
 - 7.2. Euro-QoL instrument (EQ-5D)
 - 7.3. Psychosocial Adjustment Section of the OTI
8. Changes in criminality: self-report using adapted OTI Crime Section of MAP
9. Use of other health and social services: health, social and voluntary sector services used, days off work due to illness, criminal justice sector contacts - adapted REDUCE questionnaire for cost effectiveness analysis
10. Measures of patient expectation of and satisfaction with treatment
 - 10.1. Treatment Perceptions Questionnaire
 - 10.2. Drug Use, Expectations and Satisfaction Questionnaire to measure benefits and problems with using street heroin (developed for the trial) and expectations and satisfaction of treatment received whilst on trial (developed for trial)

In addition, we are monitoring injecting practices and complications, any post dosing side effects and serious and non-serious adverse event data and collecting data on retention.

Overall study start date

01/07/2004

Completion date

30/06/2008

Eligibility

Key inclusion criteria

The selection criteria targets heroin users with a long-standing history of injecting heroin use who continue to inject heroin frequently whilst in their current episode of methadone treatment. Selection criteria include:

1. History of injecting heroin use sufficient to meet Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) criteria
2. Aged between 18 and 65 years at recruitment to study
3. In continuous methadone treatment for at least 6 months this episode
4. Regular injecting heroin use

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

150

Key exclusion criteria

1. No active significant medical (e.g., hepatic failure) or psychiatric condition (active psychosis, severe affective state) as determined by study medical officer
2. Not alcohol dependent or abusing benzodiazepines according to DSM-IV revised criteria
3. Not pregnant, breast feeding, or planning to become pregnant during the study period
4. Able and willing to participate in the study procedures (e.g., no impending prison sentence) and provide informed consent

Date of first enrolment

01/07/2004

Date of final enrolment

30/06/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

National Addiction Centre

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

South London and Maudsley NHS Foundation Trust and Kings College London (UK)

Sponsor details

c/o Dr Gill Dale

Director of Research Quality

Joint R&D Office of South London and Maudsley NHS Foundation Trust and Institute of Psychiatry

P005 Institute of Psychiatry

De Crespigny Park

London

England

United Kingdom

SE5 8AF

Sponsor type

Hospital/treatment centre

Website

<http://www.kcl.ac.uk/>

ROR

<https://ror.org/015803449>

Funder(s)

Funder type

Charity

Funder Name

Action on Addiction (UK) - Big Lottery Fund (research part of trial) (ref: PR/1/010256258)

Funder Name

National Treatment Agency (UK) - clinical part of trial (ref: 2007/08)

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?
Results article	results	29/05/2010		Yes	No
Results article	secondary outcome results	01/03/2015		Yes	No