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Addiction Recovery Clinic (ARC): adaptive opioid agonist maintenance pharmacotherapy and behavioural therapy for opioid use disorder

Submission date
29/10/2012

Recruitment status
Stopped

Registration date
04/03/2013

Overall study status
Stopped

Last Edited
11/04/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In the National Health Service (NHS) in England the front-line clinical intervention for heroin dependence is the prescription of opiate substitute medications: commonly methadone or suboxone (buprenorphine-naloxone) combined with clinical and keyworker case coordination [treatment as usual (TAU)]. The two substitution medications have been proven to be effective at reducing heroin use, overdose risk and lowering rates of acquisitive crime involvement. However, if there is use of cocaine in combination with heroin use it is less likely there will be a positive response to treatment. Whether or not there is cocaine use not all clients receiving the substitute medications experience a positive outcome. A minority will not be able to stop or will relapse into heroin use and will deteriorate progressively during treatment.

Who can participate?
Every patient who comes to Lorraine Hewitt House (LHH), an NHS treatment centre in London, UK for opiate substitution treatment over a two year period between October 2012 & September 2014 (study end date November 2015) will be asked to participate if they meet the participant selection criteria.

What does the study involve?
This study has three main aims:
1. In phase one to find out whether suboxone is more effective at achieving heroin and cocaine abstinence when compared to methadone;
2. In phase two to find out among those participants from the first phase who have not been able to stop using heroin and cocaine whether receiving a comprehensive weekly Personalised Behavioural Intervention (PBI) is more likely to result in them stopping using heroin and cocaine within 12 weeks compared to the standard clinical and keyworker case coordination (usually fortnightly)
3. To evaluate and compare the cost effectiveness of the different treatment configurations in the trial.
At phase one the participants will be randomised to one of the substitution medications (subject to clinical review) or if they have a strong preference for one of the medications they will have

the option to select their medication in consultation with the clinical team. All participants who continue into phase two will be randomised to either PBI or continued standard clinical and keyworker case coordination. The participants who do stop heroin & cocaine use by 12 week will as is routine at LHH move onto shared care treatment between the LHH clinical and keyworker team and the participants family doctor.
A battery of drug use, health, social functioning, service usage and quality of life measures will be delivered across the 24 week participation period with the main measures repeated at week 1, week 12, and week 24.

What are the possible benefits and risks of participating?
The substitution medications and basic components of the PBI have all been used extensively in the treatment of opiate dependency. It has been assessed that the study participants will be at no greater risk than would occur in the standard treatment program. There are no confirmed direct benefits to participants.
In addition to participating in the trial participants will also be given the option participating in two associated pieces of research:
1 To provide a cheek swab DNA sample for research into genetic factor links to treatment response,
2. To participate in a longer term study to find out what happens happen to participants in the study over the next 5 years.
They will be asked to allow their personal details to be flagged on three public databases: National Drug Treatment Monitoring System (NDTMS); Police National Computer (PNC); NHS Registry of Births and Deaths (NHSCR).

Where is the study run from?
Lorraine Hewitt House (LHH), an NHS treatment centre in London, UK

When is the study starting and how long is it expected to run for?
The study started in October 2012 and will run until October 2015

Who is funding the study?
Action on Addiction, a UK based charity.

Who is the main contact?
Garry Stillwell
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Contact information

Type(s)
Scientific

Contact name
Dr Michael Kelleher

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol V 1.7

Study information

Scientific Title
Effectiveness of adaptive opioid agonist maintenance pharmacotherapy and behavioural therapy for opioid use disorder

Acronym
ARC

Study objectives
1. Is there any difference between suboxone and methadone in achieving heroin and cocaine abstinence within 12 weeks of a patient starting standard clinical and keyworker coordinated treatment.
2. Among those patients who are not able to stop using heroin and cocaine within 12 weeks is there any difference in them achieving heroin and cocaine abstinence within the next 12 weeks when receiving a comprehensive Personalised Behavioural Intervention (PBI) compared to continued standard clinical and keyworker case coordination.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Surrey Borders, 25 September 2012, ref:12/LO/1429

Study design
Two phase randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

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
Opiate dependency

Interventions
11/04/2013: Please note that this trial was stopped before patient recruitment began.

Suboxone: sublingual tablets with an initial recommended once-daily dose of 0.84 mg, adjusted according to response usually, a starting dose of more than 4 mg/day with an adequate maintenance dose being in the range 1224 mg/day (with a maximum daily dose of 32 mg and a target modal dose of 16mg/d).

Methadone: (M; 60-120mg/d; modal dose range 60-80 mg/d) methadone oral solution [mixture] 1mg/1mL) Methadone induction begins using an initial dose of 1040 mg daily, which is increased by up to 10 mg daily (with a maximum weekly increase of 30 mg) until no signs of withdrawal or intoxication are seen.

Participants substitution medication will be dispensed with observed consumption on Monday to Saturday by a community retail pharmacist in the local area: there will be one take away dose provided on Saturdays for home consumption on Sunday.

Personalised Behavioural Intervention (PBI) The PBI will be delivered in 12 weekly one hour sessions. The PBI will be tailored to each clients needs and circumstances. The PBI psychologists on the ARC team at LHH will work with clients using techniques derived and adapted from four core therapeutic approaches below recommended by the National Institute of Clinical Excellence.

A menu of additional therapeutic methods will be available for use delivered according to patient preference and clinical indication e.g. 12-step facilitation).
1. Motivational enhancement therapy
2. Cognitive behavioural coping and skills training
3. Contingency management (reinforcement therapy)
4. Community reinforcement approach (network member support for recovery)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Self-report of heroin use or cocaine use during weeks via structured clinical interview and individual diary record, confirmed by rapid-result (on-site) urine screen for morphine and cocaine metabolites.

Secondary outcome measures
1. Medication compliance, treatment retention (phase 1 & 2) and psychological therapy adherence rates (phase 2)
2. Heroin craving and cocaine craving for all participants (phases 1 & 2)
3. Relative cost-effectiveness of the different treatment configurations

Overall study start date
05/10/2012

Completion date
30/10/2015

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. 18 years of age or older
2. Is able to comprehend English to the extent required by the study protocol
3. Demonstrates verbal understanding of the study patient information material, is able to provide written consent, and can understand and confirm willingness to comply with the protocol
4. Current diagnosis of opioid dependence
5. Current opioid tolerance
6. Voluntarily seeking treatment for opioid dependence and able to attend the clinic as described in the protocol
7. Lives in sufficiently stable accommodation in the community, with a personal phone
8. Can nominate at least one locator individual (e.g. a family member, friend or recovery mentor) with a verifiable address and a telephone number which we can call to assist as necessary with the arrangement of follow-up appointments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

600

Key exclusion criteria
1. Clinically significant medical condition (including pregnancy or lactating) or observed abnormalities on physical examination or laboratory investigation, including but not limited to: uncontrolled hypertension; significant heart disease (including myocardial infarction in past 12 months); angina; or any serious, potentially life-threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct; or any ECG/cardiovascular abnormality which, in the investigators judgment, is clinically significant.
2. Current criminal justice involvement with legal proceedings and, in the opinion of the Chief Investigator, is expected to fail to complete the study protocol due to incarceration or relocation from the centres catchment area.
3. Current (past 30 day) suicidal ideation/plan, or recent (past six months) suicidal ideation or suicide attempt.
4. Active, uncontrolled severe mental illness (e.g. psychosis, bipolar I disorder, schizoaffective disorder addressed in routine admissions protocol) and/or a history or evidence of organic brain disease or dementia that would compromise the participants ability to comply with the study protocol.
5. Is not currently a participant in a research study or has not been in CTIMP research study in the previous 4 months

Date of first enrolment
05/10/2012

Date of final enrolment
30/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Lead Lambeth Addictions
London
United Kingdom
SW9 8DG

Sponsor information

Organisation
King's College London (UK)

Sponsor details

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Sponsor type
University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Action on Addiction (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?
HRA research summary			28/06/2023	No	No