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NALoxone InVEstigation (N-ALIVE) Pilot Randomised Controlled Trial (RCT)

Submission date
30/09/2008

Recruitment status
No longer recruiting

Registration date
07/11/2008

Overall study status
Completed

Last Edited
14/11/2018

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=80

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC ref G0800012; MRC ID 85749; V1270808

Study information

Scientific Title

Naloxone-on-release pilot randomised controlled trial (RCT), in two prison systems and 5,600 eligible prisoners

Acronym
N-ALIVE Pilot RCT

Study objectives
The hypothesis of the main trial is that giving naloxone on release to prisoners with a history of heroin use by injection will reduce heroin overdose deaths in this population by 28% in the first 12 weeks after release. The research questions addressed in this pilot study concern establishing whether prisons and eligible prisoners participate in the numbers expected and required in the main trial, field-testing the logistics of the main trial procedures, and obtaining qualitative data around post-release heroin use, overdoses witnessed or experienced, use of naloxone, and carriage of naloxone.

As of 08/10/2010 this record has been extensively updated. At this point, the pilot study taking place in Scotland was withdrawn, and from this point the trial is taking place in England only. The overall trial dates were also updated; the initial dates were as follows:
Initial overall trial start date: 01/04/2009
Initial overall trial end date: 31/03/2011

At this time, the target number of participants were also increased to 5600; the initial target number of participants was 5400.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex 2 Research Ethics Committee on 18/05/2010

Study design
Pilot double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Heroin overdose deaths

Interventions
Amended as of 08/10/2010:
Participants randomised to the treatment arm of the study will be given a pack on release from prison containing a single-use, safety-covered and pre-loaded syringe and needle containing 2 miligrams Naloxone hydrochloride of which 800 micrograms should be given by IM injection in the event of heroin overdose.

Initial interventions at time of registration:
On randomisation, each participant is allocated a study number, which corresponds to a study pack held locally in the prison pharmacy. On release, the prisoner is issued with his/her pack. Treatment packs contain an information sheet (illustrating suitable IM injection sites), a pre-paid reply card, a carry pouch and the naloxone syringe (a single-use, safety-covered and pre-loaded syringe and needle containing 400 micrograms of naloxone hydrochloride) to be used in the event of heroin overdose. Control packs contain an information sheet (about the possible harm entailed by continuing heroin use), a pre-paid reply card, and a carry pouch, but no naloxone.

Participants who are randomised to the qualitative follow-up condition will be telephoned in either the first or second fortnight after release. Participants in Scotland will be asked to consent to completing a questionnaire if they return to prison within one year of release. Data concerning deaths and Accident and Emergency (A&E) admissions for non-fatal heroin overdoses will be accepted for up to 12 weeks after the release of each participant.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Naloxone

Primary outcome measure
1. Numbers of participating prisons and eligible prisoners
2. Number of participants contacted in qualitative follow-up
3. Questionnaire data concerning post-release heroin use, naloxone carriage and use, overdoses witnessed and experienced

Added 08/10/2010:
4. Numbers of heroin overdose deaths among participants in both arms of the pilot study

Qualitative data will be measured at either the first two or four weeks post-release, or up to one year after release in the case of questionnaires in Scotland. Data concerning rates of participation will be monitored throughout the study's two-year duration.

Secondary outcome measures
Amended as of 08/10/2010:
The following will be measured at 12 weeks post-release: numbers of non-fatal A&E admissions among participants in both arms of the pilot study

Initial information at time of registration:
The following will be measured at 12 weeks post-release:
1. Numbers of heroin overdose deaths among participants in both arms of the pilot study
2. Numbers of non-fatal A&E admissions among participants in both arms of the pilot study

Overall study start date
01/12/2010

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. Both males and females, 18-44 years old at randomisation date
2. Incarceration begun at least seven days before randomisation date
3. History of heroin use by injection
4. Likely release date within three months of randomisation date
5. Has not been randomised in N-ALIVE and then withdrawn consent prior to release from prison

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
44 Years

Sex
Both

Target number of participants
5,600

Key exclusion criteria
1. History of adverse reaction to naloxone
2. Non-resident in England, Wales or Scotland
3. Most recent index release date is within six months of randomisation date
4. Index release date is missing and participant was previously randomised in N-ALIVE in the past year
5. Participant withdraws consent prior to release
6. Participant dies prior to release
7. Exclusion from qualitative follow-up if randomised to 'No qualitative follow-up'
8. Exclusion from qualitative follow up if randomised to 'Qualitative follow-up' but participant does not consent to this part of the pilot

Date of first enrolment
01/12/2010

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL

Sponsor type
Government

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

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) (ref: G0800012; ID number 85749)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	01/10/2013		Yes	No
Results article	results	01/03/2017		Yes	No
Results article	results	01/03/2017		Yes	No