

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

Submission date 30/09/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 07/11/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/11/2018	Condition category Injury, Occupational Diseases, Poisoning	☐ 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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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 At this point, the pilot study taking place in Scotland was withdrawn, and from this point the trial is taking place in England only.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

Study type(s)

Treatment

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 milligrams 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

44 years

Sex

All

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**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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	01/03/2017		Yes	No
Results article	results	01/03/2017		Yes	No

Protocol article	protocol	01/10/2013	Yes	No
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