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Paramedic supplied 'Take Home' Naloxone: a feasibility study

Submission date
17/08/2012

Recruitment status
No longer recruiting

Registration date
15/11/2012

Overall study status
Completed

Last Edited
08/02/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Naloxone is considered to be a very safe drug with few known side effects. It is administered routinely by emergency ambulance personnel and staff in the A&E setting for emergency treatment of opioid overdose. It is often injected intravenously (given directly into the vein), but can also be given intramuscularly (given directly into a muscle). Since the 1990s interest has grown in providing 'Take Home' Naloxone (THN) to opioid users through community based drug services and some prisons. The proportion of opioid users who attend community based drug services is unknown. The attendance by paramedics at emergency calls for those who have suffered an opioid overdose presents an opportunity to distribute THN kits to those who do not routinely attend these services.
The main aim of this study is to see whether it is possible for paramedics to supply THN kits to patients they have treated and have subsequently recovered from an opioid overdose. Patients will continue to be treated as they would normally, including being advised to attend hospital for further assessment. However, those patients who demonstrate complete recovery following treatment will be offered a THN kit by the paramedic.

Who can participate?
Volunteer paramedics in an area of South Wales will be invited to participate. Adult patients (18 yrs old and above) treated for a suspected opioid overdose, who subsequently demonstrate recovery to full consciousness and full mental capacity, will be offered a THN kit by paramedics who have received training to provide the THN kits.

What does the study involve?
Paramedics will be randomly allocated to training over the first four-months of the twelve-month trial. Patients attended by paramedics who have been trained and issued THN kits for distribution will fall into the intervention group. Patients attended by paramedics following usual practice (until they receive their training and THN kits), will fall into the control group. The intervention provided by the paramedic includes a brief training package about how to recognize an opioid overdose, what to do (including calling 999), how to give the THN and where to get a further supply. At the end of their training, consenting participants will asked if they would be willing to be contacted by a member of the study team in three-months time. Those who decline follow-up will not be disadvantaged in any way and will still be given a THN kit.

What are the possible benefits and risks of participating?
The main benefit for patient participants is the opportunity to be given some simple training on how to recognize and treat an opioid overdose and a THN kit. For many paramedics, it is expected that participation in this study will lead to an enhanced level of job satisfaction, because as far as is known, this will be the first time anywhere in the world, that paramedics will be involved in the distribution of THN kits to opioid users.
We do not anticipate that this study will increase risks to participants. It is currently not known whether the distribution of THN increases risk-taking behaviour of injecting drug users. One of the aims of patient follow-up (telephone/postal questionnaire) will be to investigate this.

Where is the study run from?
This is a single centre study involving paramedics from the five ambulance stations in the Cardiff and Vale of Glamorgan area of South Wales.

When is the study starting and how long is it expected to run for?
The study aims to begin in November 2012 and is planned to run for a period of twelve-months. This study builds on a review of 999 calls in Wales which identified that calls relating to heroin poisoning were concentrated in urban areas, with Cardiff having the highest number (n=27) during the three-month study period. It is therefore hoped that 100 patients will be recruited during the twelve-month study period.

Who is funding the study?
This study is funded by Welsh Government and Welsh Ambulance Services NHS Trust.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Paramedic Administered Take Home kits: Feasible Intervention for Naloxone Distribution in Emergency Response (PATHFINDER) to opioid overdose: a feasibility study for a randomised controlled trial

Acronym
PATHFINDER

Study objectives
It is feasible for paramedics to supply 'Take Home' Naloxone kits to patients they have treated and have subsequently recovered from suspected opioid overdose and to test this intervention in a multi-centre randomised trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee, 07/12/2011, ref: 11/WA/0305

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Paramedicine

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/opioid overdose, prehospital emergency

Interventions
Following a 999 call and resuscitation for an opioid poisoning paramedics will supply 'Take Home' Naloxone (THN) to patients, for administration to peers or family members in a subsequent emergency. Paramedics will supply this intervention under the auspices of a Patient Group Direction (PGD).

This complex intervention has the following components:
1. Training for participating paramedics
2. Protocol for the supply of THN to patients who have suffered and recovered from an opioid poisoning
3. Issue of an individual 'Take Home' Naloxone (THN) kit to trained paramedics which will be replaced each time they issue their kit to a service user
4. Supply of THN and education related to its use, and resuscitation techniques and procedures, to patients

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
In this feasibility study it is inappropriate to state the primary outcome, as part of the purpose of this study is to help us to define the primary outcome for a definitive trial. Linked to the study research questions, the outcomes to be included are as follows:

Processes and outcomes of care for patients attended by participating paramedics

Numbers and proportions of patients:
1.Eligible/not eligible
2. Offered THN/not offered THN
3. THN protocol followed/not followed by crew (compliance)
4. Accepted/did not accept intervention
5. Attended A&E/did not attend A&E
6. Suffered further overdose(s) and attended by ambulance within the study period
7. Died (of any cause/of opiate poisoning) during the study period?

Time
1. From 999 call to ambulance free for next call (job cycle time)
2. Total on scene
3. To next overdose
4. Patient reported
5. 999 call

Feasibility of service user follow up:
1. Number and proportion of eligible patients consented to follow-up
2. Number and proportion successfully contacted (telephone/post)
3. Number and proportion that resulted in a completed questionnaire?

Secondary outcome measures

1. Patient experience in relation to possession and usage of THN and their views on the initiative
2. Paramedics views of the feasibility of the THN initiative including their own training; the training they provided to patients; operational practicalities; safety concerns

Overall study start date
01/11/2012

Completion date
01/11/2017

Eligibility

Key inclusion criteria
1. Patient attended following a 999 call by a paramedic that normally operates in the Cardiff & Vale of Glamorgan area, has volunteered to participate and is trained to provide THN to patients under the auspices of the THN PGD.
2. Patient is 18 years of age or older
3. Patient has regained full consciousness (GCS 15) and demonstrates full mental capacity following treatment for a suspected opiate overdose

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 participants in 1 year, in a single centre

Total final enrolment
182

Key exclusion criteria
1. Patient attended by a paramedic not trained to provide the intervention
2. Patient is 17 years of age or younger
3. Patient treated for opioid overdose, but fails to regain full consciousness/full mental capacity

Date of first enrolment
01/11/2012

Date of final enrolment
01/11/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Welsh Ambulance Services NHS Trust
Cardiff
United Kingdom
CF10 3DX

Sponsor information

Organisation
Welsh Ambulance Services NHS Trust (UK)

Sponsor details
Prehospital Emergency Research Unit
3rd Floor, Finance Building
Lansdowne Hospital
Sanatorium Road
Canton
Cardiff
Wales
United Kingdom
CF11 8PL

Sponsor type
Hospital/treatment centre

Website
http://www.was-tr.wales.nhs.uk/

ROR
https://ror.org/017qpw206

Funder(s)

Funder type
Government

Funder Name
Welsh Government (UK) ref: KE/21/01/10

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Abstract results	results presented at the 999 EMS Research Forum annual conference	01/09/2016	01/08/2019	No	No
Protocol article	protocol	20/03/2014	01/08/2019	Yes	No