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Caring for the dying at home: can lay carers safely give extra, as-needed, symptom control to their loved ones using injections under the skin?

Submission date
31/08/2016

Recruitment status
No longer recruiting

Registration date
27/09/2016

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Most people want to be cared for and die at home. As people get weaker in the last weeks or days of life, they usually can't swallow. In the UK, when this happens, it is standard practice for medicines to be given by a drip under the skin to relieve symptoms. Four symptoms are common in dying people: pain, agitation, nausea and noisy breathing (rattle). These are called breakthrough symptoms. These can happen even when a drip is already in place. When they do, a family member is advised to call a healthcare professional (HCP), usually a district nurse. The nurse will visit and give the patient an injection under the skin, but it can take a long time, often much more than an hour, for the nurse to arrive and give the medicine. This wait can be distressing for patient and carer and the symptom can worsen by the time the nurse arrives. Carers tell us that this makes them feel powerless to help their loved ones. In some countries, like Australia, carers are trained to give symptom-relieving medicine to their dying relatives at home. It is not known whether this approach would be welcomed in the UK, so it needs to be tested. Before doing a large study, it is good practice to first test the feasibility in a smaller group of patients. The aim of this study is to find out whether it is feasible and acceptable for carers to administer medication to dying patients for breakthrough symptoms.

Who can participate?
Dying patients in the last weeks of life and their carers, aged over 18

What does the study involve?
Participants are randomly allocated to either the 'usual care' or 'new care' group. Carers in the 'usual care' group are asked to call a HCP if their loved one has breakthrough symptoms. Carers in the 'new care' group are trained how to recognise symptoms, to give injections and then see if they work to relieve the symptom. Carers in both groups are asked to keep a diary of symptoms and treatments. They are invited to talk about how they found the study and the experience of giving injections.

What are the possible benefits and risks of participating?
Information from this study will help the researchers to understand if a large study, to give a final answer, is possible. Possible benefits of carers administering medication include more rapid symptom control for the patient, and the carer feeling more in control. The risks are increased anxiety for the carer taking on this new role, which should be lessened by the good training the study will provide.

Where is the study run from?
1. North Wales Centre for Primary Care Research (UK)
2. Marie Curie Palliative Care Research Centre (UK)
3. Sue Ryder Hospice Gloucestershire (UK)

When is the study starting and how long is it expected to run for?
November 2016 to September 2019

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Prof. Clare Wilkinson (public)
2. Dr Marlise Poolman (scientific)

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
227970

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HTA 15/10/37

Study information

Scientific Title
Carer administration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: a UK study (CARIAD)

Acronym
CARIAD

Study objectives
Carer-administration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients is feasible and acceptable in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 1, 03/08/2017, ref: 17/WA/0208

Study design
Developmental work, including qualitative work, followed by a pragmatic, multi-centre, randomised feasibility trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
End of life care

Interventions
Firstly, the trialists will ensure that everyone understands it is legal for carers to give symptom-relieving injections to dying patients as long as they are supported to do so. A time-tested education package made by the trialists' Australian partners will be reworked for UK patients, carers and healthcare professionals. An expert consensus group (comprising of carers and healthcare professionals) will hold workshops on to do this, and to decide how best to explain the study to carers and patients. Patients and their carers will then be randomised to either 'usual care' or 'new care':
1. Carers in the 'new care' group will be trained how to recognise symptoms, to give injections and then to see if they work to relieve the symptom.
2. Carers in the 'usual care' group will be asked to call a healthcare professional if their loved one has breakthrough symptoms (pain, agitation, nausea and noisy breathing [rattle]).
Carers in both groups will be asked to keep a diary of symptoms and treatments. They will be invited to talk about how they found the study and the experience of giving injections.

Intervention Type
Other

Primary outcome(s)
As this is a feasibility trial, one of the goals is to establish the best primary and secondary outcome measures. The most likely candidates for primary outcome measures for a future definitive trial are:
1. Overall symptom burden/distress in the last 7 days of life, measured using the Family MSAS-GDIA either after the patient's death or amended for use on a daily basis
2. Quality of life of carers, incorporating elements of control and self-efficacy, measured using QOLLTI-F by a research nurse every 48 hours

Key secondary outcome(s))
Time to symptom relief, calculated using data items from the Carer Diary, collected from the carer after the patient has died

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Dyads of dying patients and their home-based carers
2. Adult patients in the last weeks of life
3. Who are likely to use the oral route for medication
4. Have expressed a preference to die at home
5. Have a family carer who is over 18
6. Carer is willing to have this extended role
7. Carer is willing to have subcutaneous injection training

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Patient or carer is under 18
2. Patient or carer not willing to entertain concept of lay carer administering subcutaneous medication
3. Patient or carer has a known history of substance abuse
4. Patient has had previous known adverse reactions to substance meds
5. Clinician judges that risk assessment criteria are not met for a dyad

Date of first enrolment
10/01/2018

Date of final enrolment
15/03/2019

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
North Wales Centre for Primary Care Research
Bangor University
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LL13 7YP

Study participating centre
Marie Curie Palliative Care Research Centre
United Kingdom
CF14 4YS

Study participating centre
Sue Ryder Hospice Gloucestershire
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Sponsor information

Organisation
Bangor University

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Clare Wilkinson and Marlise Poolman on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2020	28/10/2022	Yes	No
Results article		12/06/2025	16/06/2025	Yes	No

Protocol article	protocol	07/02/2019		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes