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Conducting research in palliative care: finding the best way forward - Cluster randomisation or randomised consent as an appropriate methodology for trials in palliative care: a feasibility study

Submission date 03/02/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/02/2004	**Overall study status** Completed	
Last Edited 05/07/2018	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Conducting research in palliative care: finding the best way forward - Cluster randomisation or randomised consent as an appropriate methodology for trials in palliative care: a feasibility study

Acronym
PEACE

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval for this feasibility study was granted by the North Wales Health Authority Research Committee (West, Central and East sub-committees).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Palliative care

Interventions
Not prescribing an anti-emetic as standard treatment on commencement of a syringe driver unless patient is symptomatic.

The study utilises a crossover design and is taking place at two sites within the North West Wales NHS Trust.

One site has been independently randomised (by the University of Wales Bangor) to a cluster randomised method for three months. All dying patients in that cluster will not receive an anti-emetic on commencement of a syringe driver. If the patient becomes nauseous or vomits an anti-emetic will be available and administered immediately. Patients falling into this category will form a sub-group. Patients in the cluster site are unaware that the study is taking place, consent to participate is given by the cluster gatekeeper in this case the ward sister, who also has the right if she wishes to withdraw her cluster from the study.

The second site participating in the study have been allocated to use the randomised consent or Zelen method for a period of three months. In this condition patients are approached for consent after randomisation has taken place. Randomisation is being undertaken by the University of Wales Bangor. When a patient is in the last days of life and about to start on a syringe driver and they are asymptomatic a phone call is made to the University and randomisation occurs. Either they are allocated to receive an anti-emetic (Standard Treatment) or not. If they are in the non-standard group then they are approached for their informed consent. Again any patients that are in the non-standard group that become symptomatic will immediately receive medication and their data allocated to the sub-group of the study.

After the three month period the two sites will receive a short de-briefing and then "swap" or cross over the two methods.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2004

Completion date
01/05/2005

Eligibility

Key inclusion criteria
All patients identified as dying and being cared for on an Integrated Care Pathway at two sites within the Trust who are about to commence syringe driver delivered medication.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/2004

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Palliative Care Department
Caernarfon
United Kingdom
LL55 2YE

Sponsor information

Organisation
North West Wales NHS Trust (UK)

Sponsor details
Penrhosgarnedd
Bangor
Wales
United Kingdom
LL57 2PW

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/04a496k07

Funder(s)

Funder type
Government

Funder Name
North West Wales NHS Trust Research and Development Fund (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?
Protocol article	protocol	27/04/2004		Yes	No
Results article	results	01/12/2006		Yes	No