

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/02/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/07/2018	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Diagnostic

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

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	01/12/2006		Yes	No
	protocol				

[Protocol article](#)

27/04/2004

Yes

No