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Opioids in the management of breathlessness in advanced heart failure

Submission date 03/05/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/09/2007	**Overall study status** Completed	
Last Edited 04/07/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
R&D number RO452

Study information

Scientific Title

Study objectives
Opioids are currently used in the management of breathlessness in palliative patients at the end of life. There is a small but growing evidence base regarding the use of opioids to manage breathlessness in lung cancer and Chronic Obstructive Pumonary Disease (COPD). A pilot placebo controlled crossover study involving oramorph in ten heart failure patients demonstrated symptom improvement and two studies involving opioids in exercise revealed an improvement in exercise tolerance. Morphine is also used clinically to treat acute pulmonary oedema. The manner in which opioids improve breathlessness is unclear, but is likely to represent a combination of local effects in the lung and heart, effect at the respiratory centre in the brain and neurohumeral effects. Our aim is to demonstrate a symptom benefit regarding breathlessness with opioids and to determine if this is a class effect and whether opioids that interact with different opioid receptors have different outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Leeds East Ethics Committee on the 9th October 2007 (ref: 07 /H1306/110).

Study design
This study is a three arm randomised double blind placebo controlled clinical crossover trial. Participants and observers will remain blinded throughout.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic heart failure

Interventions
Please note that as of 29/04/2008 the anticipated start date of this trial was changed to 01/05 /2008; the previous start date was 01/07/2007.

The two active intervention arms involve low dose oral liquid morphine (oramorph 5 mg four times a day [QDS]) and oral oxycodone liquid (oxynorm 2.5 mg QDS). The sequence of interventions will be randomised for each participant and all participants will receive all three treatment arms. Participants will be invited to take the medication (oramorph, oxynorm or placebo) for four consecutive days. There will be daily assessments of breathlessness and side effects during this time. A three-day washout period will occur before commencing the next treatment in sequence.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Morphine (oramorph), oxycodone (oxynorm)

Primary outcome(s)
Severity of breathlessness as measured by the Borg validated score for breathlessness and 11 point Numerical Rating Scale (worst, average and current readings), measured daily whilst taking the trial medications.

Key secondary outcome(s))
1. Distress from breathlessness, measured on days one and four for each trial medication (the first and last days participants take it)
2. Satisfaction and coping, measured daily whilst taking the trial medications
3. Breathlessness descriptors, measured on days one and four for each trial medication (the first and last days participants take it)
4. Adverse effect scores, measured daily whilst taking the trial medications
5. Quality of life, measured on days one and four for each trial medication (the first and last days participants take it)

Completion date
01/12/2008

Eligibility

Key inclusion criteria
1. New York Heart Association (NYHA) grade three to four chronic heart failure with systolic dysfunction on echocardiography
2. Receiving optimal medical management (diuretics and Angiotensin Converting Enzymes [ACE] inhibitors/angiotensin 2 antagonists) stable for the past month
3. Aged 18 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Inadequate renal function (Glomerular Filtration Rate [GFR] less than 30 ml/min on Cockroft /Gault formula)
2. Morphine allergy
3. Currently receiving opioid therapy

Date of first enrolment
01/05/2008

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Academic Cardiology
Hull
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Hull York Medical School (HYMS) Clinical Fellowship Scheme (funded by the NHS local Strategic Health Authority) (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	01/09/2011		Yes	No