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Bolus versus continuous study

Submission date 26/05/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/07/2010	**Overall study status** Completed	
Last Edited 15/11/2017	**Condition category** Signs and Symptoms	

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
2.8022010

Study information

Scientific Title
Comparison of the effects of intermittent boli to simple continuous infusion on patients' global perceived effect in intrathecal therapy for pain

Study objectives

This study aims to compare the effect of the same daily dose of intrathecal analgesia administered by intermittent boli compared to a simple continuous infusion on the Patient-reported Global Impression of Change (PGIC) related to their intrathecal pain relief.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UK: Leicestershire, Northampton and Rutland Research Ethics Committee 2 (now East Midlands-Northampton REC), 03/08/2010
2. Switzerland: ref: 59/10

Study design
Randomised double-blind two-period cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe chronic pain

Interventions
Non-clinical interventions:
1. Informed consent will be obtained by the Principal Investigator, from the patient prior to enrolment of patient into the study. This will occur only once and will take approximately 30 minutes.
2. Demographic data will be collected from the patient, by the Blinded assessor, once consent has been gained, and this will take about 5 minutes to complete
3. Five day pain diary will be completed by the patient in their home. This will be done at baseline, and at the end of each 2-week period.
4. EQ-5D Questionnaire will be completed by the patient in the Pain Clinic at baseline and at the end of each 2-week period, and this will take approximately 5 minutes to complete
5. Visual Analogue Scale (VAS) measure of patients pain relief will be completed by the patients in the Pain Clinic at the baseline, and at the end of each 2-week period, and this will take approximately 1 minute to complete
6. Patient Global Impression of Change (PGIC) questionnaire will be completed by the patient in the clinic at the end of each 2-week period, and it will take approximately 2 minutes to complete
7. Telephone contact will be carried out by the blinded assessor, to the patient at the end of each 2-week period, and will last approximately 10 minutes each

Clinical interventions:
1. Physical examination of the participants will be conducted by the Principal Investigator on two occasions, to ascertain fitness to commence, or to continue trial with procedures
2. Programming of the ITDD device by the Principal Investigator and the unblinded Research Nurse to either intermittent bolus or simple continuous flow. This will last fifteen minutes, and will be performed on three different occasions.
3. Recording vital signs of blood pressure, pulse rate, respiratory rate, temperature and oxygen saturations, following programming of the intrathecal device. There will be eight sets of vital

signs recorded, and each set will last approximately five minutes. This is done to monitor patient safety.
4. Observations of the patient post-programming will be done in clinic at the end of programming for 2 hours each, to ascertain patient safety

As this is a randomised double crossover design study, the patients are acting as their own controls. As they crossover from the study group (multiple boluses) to the control condition (continuous infusion) the total drug dose/day remains the same on both arms. There is a one week run in period followed by 2 weeks on either arm of the study. The study ends at completion of the second arm, therefore there is a total duration of 5 weeks. No longer term follow up is planned as the patients are clinically followed up regularly at 6 week intervals.

Intervention Type
Device

Primary outcome(s)
Patient Global Impression of Change (PGIC), a self-evaluation of the patient's overall change since the start of the study, will be completed at the end of each 2 week period using a 7-point Likert scale (very much improved, much improved, minimally improved, no change, minimally worse, much worse, very much worse). The PGIC was chosen as it will allow the patient to balance a potential improvement in pain relief with a potential worsening in side effects.

Key secondary outcome(s))
Conducted at baseline and the end of each 2-week period:
1. Visual Analogue Scale (VAS) of pain relief patients will score their pain on a 100 mm line anchored with 'no pain' at the 0 mm end and 'worst pain imaginable' at the 100 mm end
2. EQ-5D is a health related quality of life questionnaire which is divided into five dimensions: mobility, self-care, usual activity, pain/discomfort and anxiety/depression
3. Patient preference - at the end of the study, patients will be asked to choose which of the two programming methods they prefer
4. Observer guess of the group - to discover how successful the blinding is, the blinded assessor and the patient will be asked if they can identify which programming method has been allocated. If neither can identify the method, this will show the blinding has been successful, and refute any claims of bias.

Completion date
01/09/2012

Eligibility

Key inclusion criteria
1. Patients implanted with a programmable intrathecal drug delivery (ITDD) device
2. Achieved stable pain relief on continuous flow
3. Capable of giving informed consent
4. Willing to sign the Informed Consent Form
5. Male or female, aged between 18 and 65 years

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Fail to give informed consent
2. Are incapable of answering the questionnaires (PGIC, EuroQoL [EQ-5D], Visual Analogue Scale [VAS] score) for physical or psychological reasons
3. Have non-programmable ITDD device
4. Have Patient Therapy Manager (PTM) devices
5. Are using ziconotide intrathecal therapy
6. Are programmed with bolus doses (flex doses)
7. Have severe limitation in function and mobility
8. Are pregnant or lactating
9. Are not practicing a safe method of birth control

Date of first enrolment
01/09/2010

Date of final enrolment
01/09/2012

Locations

Countries of recruitment
United Kingdom

England

Switzerland

Study participating centre
The James Cook University Hospital
Middlesbrough
United Kingdom
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Sponsor information

Organisation
South Tees Hospitals NHS Trust (UK)

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Industry

Funder Name
Medtronic Europe S.A. (Switzerland)

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	01/05/2017		Yes	No