

# Bolus versus continuous study

<b>Submission date</b> 26/05/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/11/2017	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Sam Eldabe

**Contact details**  
Cheriton House  
The James Cook University Hospital  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW  
+44 (0)1642 282417  
sam.eldabe@stees.nhs.uk

## 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

TS4 3BW

**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?
<a href="#">Results article</a>	results	01/05/2017		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes