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Evaluation of a new device (patent publication GB 2366729) for identification of the epidural space

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 12/12/2013	**Condition category** Surgery	

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

N0515163806

Study information

Scientific Title

Study objectives
To evaluate a new device (patent publication GB2366729) for identification of the epidural space. In particular to test the claimed advantages:
1. Reducing failure rates for epidural insertions which are presently quoted in the literature at a range of 7-23% or an average of 15%
2. Reducing the number of attempts before achieving a successful epidural insertion
3. Reducing the insertion time
4. Ease of use scale
5. Steep or zero learning curve

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Anaesthesia

Interventions
Randomised Controlled Trial

Intervention Type
Device

Phase

Not Specified

Primary outcome measure
Detailed in protocol and its supplements. Will be misleading to attempt to cover that in this small space.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2002

Completion date
30/10/2007

Eligibility

Key inclusion criteria
We have estimated that 400 patients (200 Epidrums) will be required for this study. This was estimated for the required significance of difference at a p value of less than 0.05 and for the average failure rate quoted above, number of attempts at epidural needle insertion and ease of its use scale, and the expected differences in learning curves. We estimated that the power of this study with the number of patients above will not be enough for incidence of complication such PDPH, and neurological complications which will be tested later in larger multi-centre trials. Two hundred patients in each group, sixteen to eighty years.

Inclusion criteria:
1. Patients over 18 and under 80 years of age
2 Clinical need for epidural injection
3. Absence of any contraindication to epidural injection, relative or absolute

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
400

Key exclusion criteria

1. Patients under 18 and over 80 years of age
2. Bleeding tendency, local infection, bacteraemia or septicaemia
3. Unable or unwilling to give consent
4. All other relative clinical contraindications to epidural injection or anaesthesia

Date of first enrolment
01/12/2002

Date of final enrolment
30/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaethetics Level 4J
Harrow
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North West London Hospitals NHS Trust

Funder Name
NHS R&D Support Funding

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