# The effect of an ilio-inguinal block in appendectomy on post operative pain and hospital stay

Submission date	Recruitment status	[_] Рго
28/09/2007	No longer recruiting	[] Pro
Registration date	Overall study status	[] Stat
28/09/2007	Completed	[X] Res
Last Edited	Condition category	[] Indi
06/07/2009	Signs and Symptoms	

### Plain English summary of protocol

Not provided at time of registration

### Contact information

Type(s) Scientific

Contact name Dr Simon Middleton

### **Contact details**

Deparment of General Surgery **Royal Berkshire Hospital** London Road Reading United Kingdom **RG1 5AN** 

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers N0199192286

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### Study information

Scientific Title

#### **Study objectives**

Does the use of local anaesthetic nerve blocks to numb the operation site, once the patient is anaesthetised, reduce port operative pain in patients undergoing appendectomy? This will be compared to infiltration of the skin alone with local anaesthetic.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Not provided at time of registration

**Study design** Randomised prospective trial with patient and ward staff blinded to intervention

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

Participant information sheet

Health condition(s) or problem(s) studied Signs and Symptoms: Pain

#### Interventions

1. Group A: local infiltration of skin prior to incision with bupivacaine according to weight. 2. Group B: half the bupivacaine by weight infiltrated into the skin prior to incision. As incision deepened second half of bupivacaine given under direct vision deep to external oblique, lateral to the incision, to create field block.

**Intervention Type** Other

**Phase** Not Specified

Primary outcome measure

- 1. Post operative pain in recovery: by questionnaire in recovery
- 2. Post operative pain on ward at 4 and 8 hours post op: by questionnaire
- 3. Post operative pain at 24 hours or at discharge, whichever is sooner.

4. Hours from operation to discharge.

#### Secondary outcome measures

Not provided at time of registration

Overall study start date 07/03/2007

**Completion date** 30/06/2007

# Eligibility

#### Key inclusion criteria

All open appendectomies undertaken for acute appendicitis at Royal Berkshire Hospital. At time of analysis different sub groups formed according to operative findings: gangrenous / perforated appendix or normal appendix.

Participant type(s) Patient

**Age group** Not Specified

**Sex** Not Specified

Target number of participants

90

#### Key exclusion criteria

- 1. Laparoscopic appendectomies.
- 2. Appendix removed at time of planned laparotomy (i.e. not through small incision).

These exclusion criteria exist as we wish to judge the effect of local anaesthetic on post operative pain. Where a different size wound is left (laparoscopic or laparotomy) it would be an unfair comparison.

Where the initial operation is appendectomy via a lanz incision but an alternative pathology is found or the wound is extended for a laparotomy then the patient will be included in the study until the time of analysis.

Date of first enrolment 07/03/2007

Date of final enrolment 30/06/2007

### Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre Deparment of General Surgery** Reading United Kingdom RG1 5AN

### Sponsor information

**Organisation** Record Provided by the NHSTCT Register - 2007 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** Royal Berkshire NHS Foundation Trust (UK)

# **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

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/05/2010		Yes	No