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

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 06/07/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0199192286

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
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SW1A 2NL
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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?
Results article	results	01/05/2010		Yes	No