ISRCTN60295543 https://doi.org/10.1186/ISRCTN60295543

Continuous TAP blocks for major gynaecological surgery

Submission date 14/06/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/06/2016	**Overall study status** Completed	
Last Edited 24/02/2021	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-pain-control-after-surgery-for-a-gynaecological-cancer-tapas

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

16HH3332

Study information

Scientific Title
A double blind, randomized, controlled study to assess the efficacy of continuous transversus abdominis plane (TAP) blocks for analgesia and enhanced recovery following major gynaecological surgery

Acronym
TAPAS

Study objectives
Continuous TAP blocks are more effective than the same amount of systemic local anaesthetic

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Dulwich NREC, 05/08/2016, ref: 16/LO/1250

Study design
Single-centre, double blind, randomized, controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Pain after major gynaecological oncology surgery

Interventions
This is a single centre randomised controlled study investigating the effects of bilateral transversus abdominis blockade on post-operative analgesic requirement after major gynaecological surgery. It is impossible to blind all of the clinical team (someone has to know whether they have performed a TAP block) but unblinded staff will not meet the patient post-operatively.

Participants are randomly allocated to one of two groups. Those in group 1 (control group) are given a subcutaneous infusion of local anaesthetic. Additional post-operative analgesia using paracetamol and patient controlled morphine. Those in group 2 (treatment) are given a TAP infusion of local anaesthetic. Additional post-operative analgesia using paracetamol and patient controlled morphine.

While in hospital, the participant is asked a few questions about pain, nausea, vomiting and bowel action each day. On day 3, there are asked to attend a 40 question interview. They are also requested to blow into a machine to measure PEFR daily from the second to the fourth post-operative day (unless discharged earlier). On two days an additional 10ml blood will be drawn to measure lidocaine concentration. These will be drawn at the same time as routine samples.

Intervention Type
Drug

Phase
Not Applicable

Primary outcome measure
Morphine use via a PCA pump. The amount used will be recorded daily but the primary outcome will be the amount used up to 0800hr on Day 3 (after which the lidocaine infusion will be stopped)

Secondary outcome measures
1. Pain score: Patients will be asked for their pain score (none, mild, moderate or severe) every morning at rest, on taking a deep breath, and on coughing
2. Morphine side effects: Episodes of nausea and vomiting over the last 24 hours will be recorded daily. The day of the first post-operative bowel action will be noted
3. Respiratory function: Peak expiratory flow rate will be recorded pre-operatively and daily from post-operative day 1
4. Operative and clinical outcomes data, including the extent of the abdominal incisions and the duration of hospital stay
5. Adverse events will also be recorded

Overall study start date
02/04/2014

Completion date
01/11/2019

Eligibility

Key inclusion criteria
Patients aged 30-75 undergoing elective gynaecological oncology surgery

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
42

Total final enrolment
19

Key exclusion criteria
1. Patients unable to give informed consent (mainly language difficulty)
2. Patients with contraindications to drugs specified in the protocol or participation in another medical trial involving medications

Date of first enrolment
11/08/2016

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hammersmith Hospital
Ducane Road
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Joint Research Governance Office, Imperial College Healthcare Trust

Sponsor details
St Mary's Hospital, Praed Street
London
England
United Kingdom
W2 1PG

Sponsor type
Hospital/treatment centre

Website
www.ic.ac.uk/clinicalresearchgovernanceoffice

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Imperial College Healthcare Trust, Department of Anaesthetics and Critical Care

Results and Publications

Publication and dissemination plan
Results will be published in a peer-reviewed journal.

Intention to publish date
31/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Geoff Lockwood at g.lockwood@imperial.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		23/06/2016	24/06/2016	No	Yes
HRA research summary			28/06/2023	No	No