

Continuous TAP blocks for major gynaecological surgery

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

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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Single-centre, double blind, randomized, controlled study

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

Completion date

01/11/2019

Eligibility

Key inclusion criteria

Patients aged 30-75 undergoing elective gynaecological oncology surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Hammersmith Hospital

Ducane Road

London

United Kingdom

W12 0HS

Sponsor information

Organisation

Joint Research Governance Office, Imperial College Healthcare Trust

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

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

[HRA research summary](#)

[Participant information sheet](#)

Details	Date created	Date added	Peer reviewed?	Patient-facing?
		28/06/2023	No	No
	23/06/2016	24/06/2016	No	Yes