ISRCTN91628176 https://doi.org/10.1186/ISRCTN91628176

An open randomised comparison of the clinical effectiveness and costs of protocol driven opioid analgesia, celiac plexus block, or thoracoscopic splanchnicectomy for pain relief in patients with abdominal malignancy

Submission date 25/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/04/2003	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 19/10/2018	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-pain-relief-for-people-with-advanced-abdominal-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 97/09/53

Study information

Scientific Title
An open randomised comparison of the clinical effectiveness and costs of protocol driven opioid analgesia, celiac plexus block, or thoracoscopic splanchnicectomy for pain relief in patients with abdominal malignancy

Acronym
NaTTS

Study objectives
Thoracoscopic splanhnicectomy (TS) or percutaneous celiac plexus block (CPB) may reduce the need for opioids, and their side effects, and may improve quality of life in patients with painful upper GI cancer. This study aims:
1. To show better early pain relief when protocol driven opioid analgesia is supplemented with TS or CPB. This will be determined as the percentage of patients who obtain good pain relief 1 & 2 weeks after study entry (primary end point).
2. To determine the effect at 1, 2 weeks and monthly intervals until death of these interventions on opioid consumption, opioid side effects, and health related quality of life.
3. To compare survival time in the three groups of patients.
4. To evaluate total health care costs (to the hospital, community services and patient) between study entry and death in the three groups and to determine as appropriate the cost-utility, cost effectiveness or mean cost per patient of TS or CPB. From this to form an evidence based judgement of the cost-effectiveness of wider application of this new technology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gastrointestinal cancer

Interventions
Protocol-driven opioid analgesia, celiac plexus block, or thoracoscopic splanchnicectomy for pain relief in patients with abdominal malignancy.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
To show better early pain relief when protocol driven opioid analgesia is supplemented with TS or CPB. This will be determined as the percentage of patients who obtain good pain relief 1 & 2 weeks after study entry (primary end point).

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/10/2005

Eligibility

Key inclusion criteria
Patients with gastrointestinal cancer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/02/2002

Date of final enrolment
31/10/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University of Southampton (UK)

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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	01/10/2009		Yes	No
Plain English results				No	Yes