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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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).

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2002

Completion date
31/10/2005

Eligibility

Key inclusion criteria
Patients with gastrointestinal cancer

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
330

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
England

United Kingdom

Study participating centre
Southampton General Hospital
Southampton
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Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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?
Plain English results				No	Yes
Results article	results	01/10/2009		Yes	No