

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/10/2018	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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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 splachnicectomy 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

United Kingdom

SO16 6YD

Sponsor information

Organisation

University of Southampton (UK)

Sponsor details

University Road

Southampton

England

United Kingdom

SO17 1BJ

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