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A study investigating whether hyoscine butylbromide improves image quality of computed tomography (CT) when giving stereotactic ablative radiotherapy (SABR) in the abdomen and pelvis

Submission date 01/04/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/04/2019	**Overall study status** Completed	
Last Edited 13/08/2021	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Stereotactic ablative radiotherapy (SABR) is a type of radiotherapy where a high dose of radiation is given very accurately in a small number of treatments to an area of cancer and a limited region of normal tissue around it. It can be used to treat cancer in the lower abdomen and pelvis. Cone beam computed tomography (CBCT) scans are performed before each SABR treatment to check the treatment will be given to the right place. These scans are negatively affected by bowel movement. Hyoscine butylbromide (HBB) is routinely used in x-ray departments to reduce bowel movement and improve image quality but it is not used in radiotherapy. Improving image quality would potentially improve the ability to accurately give SABR to patients. HBB is well tolerated by most patients. The aim of this study is to find out whether hyoscine butylbromide improves the image quality of computed tomography (CT) when giving SABR in the abdomen and pelvis.

Who can participate?
Patients aged 18 or over with limited areas of cancer in the lower abdomen and pelvis who are being treated with SABR in Leeds and other UK radiotherapy centres.

What does the study involve?
Participants are given HBB as an injection into the muscle of the buttocks before alternate SABR treatments. Giving HBB on alternate SABR treatments would help show whether any improvement in CBCT image quality was due to HBB or due to variation in that participant's bowel motion. A questionnaire is used to ask participants about any side effects from HBB, and if radiotherapy staff feel HBB could be used as a routine part of giving SABR. No further requirements of participants are needed once their SABR treatment has finished.

What are the possible benefits and risks of participating?
Participants will not benefit directly but if HBB improves CBCT image quality this could help improve the accuracy of SABR for future patients. Participants might get side effects from HBB but these are not expected to be serious because it is used routinely in the x-ray department. Patients may notice temporary blurring of vision, dry mouth, dizziness or palpitations (feeling of heart racing). Other side effects, including those that are serious, are rare. HBB to patients will not be given to patients with serious heart problems.

Where is the study run from?
The study is run from the University of Leeds, UK. It may also open in other UK radiotherapy centres.

When is the study starting and how long is it expected to run for?
May 2019 to January 2021

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr Finbar Slevin
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
40521

Study information

Scientific Title
HBB-SABR: A feasibility study investigating the effect of hyoscine butylbromide injections on cone beam CT quality when delivering abdomino-pelvic stereotactic ablative radiotherapy (SABR)

Acronym
HBB-SABR (version 1.0)

Study objectives
1. The null hypothesis of the primary endpoint is that administration of HBB does not result in increased proportion of images with an improved Likert-type scale score.
2. The null hypotheses of the secondary endpoints are that incorporation of intramuscular HBB into a clinical SABR workflow is neither feasible within the radiotherapy department schedule nor is it acceptable to patients because of toxicity or lack of tolerance for receiving an intramuscular injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/05/2019, Yorkshire and Humber – Leeds West Research Ethics Committee (NHSBT, Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; Tel: +44 (0)207 104 8086; Email: nrescommittee.yorkandhumber-leedswest@nhs.net), REC ref: 19/YH/0074

Study design
Non-randomized; Interventional; Design type: Process of Care, Drug, Radiotherapy, Imaging

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Limited areas of cancer in the lower abdomen and pelvis

Interventions
Patients will receive intramuscular HBB 20 mg (into upper outer quadrant of gluteal muscle) on fractions 1, 3 and 5 of a five-fraction SABR treatment (or fractions 1 and 3 of a three-fraction regimen). On fractions 2 and 4 (or fraction 2) no injection of HBB will be given. The injection will be administered following check of the drug name, dose and expiry date. Patient identity (by means of name and date of birth) and allergy status will be confirmed prior to administration. An aseptic non-touch technique will be used.

Following delivery of intramuscular HBB patients will proceed with pre-treatment CBCT, target matching and set up adjustment, delivery of SABR fraction and post-treatment CBCT as per departmental protocol.

Following delivery of SABR fraction patients will be asked not to drive for 60 minutes following administration of HBB. This is to allow any blurred vision that may occur with HBB to settle. They will be asked to attend hospital immediately if they develop painful blurred vision in one or both eyes after receiving HBB, as this may be a symptom of previously undiagnosed acute angle closure glaucoma.

Patients will be asked to seek medical advice in the event of any other side effect that may be secondary to HBB including acute urinary retention, chest pain, breathlessness, dizziness, palpitations, rash, angio-oedema, abdominal pain or vomiting. Patients in Leeds Cancer Centre will be provided with the contact details for the on call oncology nurse practitioner for any clinical advice. At other trial sites participants should be provided with contact details for their respective on call oncology advice line.

After the final fraction patients and radiographer staff involved in their care will be asked to complete an end of treatment questionnaire. The patient questionnaire includes questions relating to tolerance for receipt of HBB intramuscular injection. Toxicity will be assessed by a member of the trial team using CTCAE version 5 criteria. The staff questionnaire includes questions about acceptability of including a HBB injection within a clinical SABR workflow and impact on department scheduling.

Following completion of SABR treatment analysis of CBCT images with and without HBB will be performed by multiple experienced observers using a four-point Likert-type scale.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hyoscine butylbromide

Primary outcome measure
Cone beam CT image quality when HBB administered, determined by proportion of images with improved Likert-type scale results at end of SABR treatment

Secondary outcome measures
1. Feasibility of administration of intramuscular HBB within a clinical abdomino-pelvic SABR workflow, measured using questionnaire at time of final SABR fraction
2. Patient and radiotherapy department staff acceptability of intramuscular HBB injection, assessed using questionnaire at time of final SABR fraction

Overall study start date
01/05/2019

Completion date
11/01/2021

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Capacity to give written, informed consent
3. WHO performance status 0-2
4. Histologically or radiologically confirmed lymph node or bone oligometastatic disease in the abdomen or pelvis limited to < = 3 lesions in total
5. All metastases must be visible on imaging and be suitable for stereotactic ablative radiotherapy in the lower abdomen and pelvis as per the NHS England Commissioning through Evaluation criteria or the Conventional care versus radioablation (stereotactic body radiotherapy) for extracranial oligometastases (CORE) study
6. Predicted life expectancy > 6 months
7. No co-morbid conditions likely to impact on the advisability of SABR (e.g. previous inflammatory bowel disease, previous abdominal or pelvic surgery, significant bladder instability or urinary incontinence, clinically significant renal or hepatic impairment)
8. No comorbidities likely to impact on safety of administration of HBB (for example severe cardiac disease, recent cardiac event, cardiac tachyarrhythmias, angle closure glaucoma, myasthenia gravis, pyloric stenosis, porphyria, severe ulcerative colitis, paralytic ileus, obstructive uropathy or allergy to HBB)
9. No bilateral prosthetic hips- this would prevent use of volumetric modulated arc therapy (VMAT) solution for SABR
10. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol; those conditions should be discussed with the patient before registration in the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Total final enrolment
20

Key exclusion criteria
No comorbidities likely to impact on safety of administration of HBB (for example severe cardiac disease, recent cardiac event, cardiac tachyarrythmias, angle closure glaucoma, myasthenia gravis, pyloric stenosis, porphyria, severe ulcerative colitis, paralytic ileus, obstructive uropathy or allergy to hyoscine butylbromide)

Date of first enrolment
01/05/2019

Date of final enrolment
18/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James's University Hospital
Beckett Street
Leeds
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Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
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SW3 6JJ

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
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OX3 9DU

Study participating centre
The Christie NHS Foundation Trust
Wilmslow Road
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M20 4BX

Sponsor information

Organisation
University of Leeds

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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: C309/A21993

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Intention to produce a brief lay summary of the research outcomes in paper format and provide this to participants (having checked that they are still alive) once the study has finished

Intention to publish date
01/05/2021

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 Ann Henry, Associate Professor in Clinical Oncology (a.henry@leeds.ac.uk). Type of data: Likert scale scores, prevalence of factors negatively influencing image quality, responses to questionnaires. Data anticipated to be available from approximately 3 months following completion of study for 5 years. Access to data will be considered on an individual basis per each approach. Consent from participants was obtained for use of anonymised data in further research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		18/01/2019	02/04/2019	No	No
Results article	results	29/07/2021	13/08/2021	Yes	No
HRA research summary			28/06/2023	No	No