ISRCTN91527768 https://doi.org/10.1186/ISRCTN91527768

Extra-corporeal High Intensity Focused UltraSound for primary Sacrococcygeal bone Tumours

Submission date 20/04/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/06/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/08/2024	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-of-hifu-for-bone-cancer-in-lower-spine

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
Extra-corporeal high intensity focused ultrasound for primary sacrococcygeal bone tumours: Phase IIb trial of clinical efficacy

Acronym
HIFUSST

Study objectives
This study intends to study the hypothesis that high intensity focused ultrasound can be used to treat primary malignant osseous tumours of the sacrococcygeal spine in terms of reducing patients' symptoms and prolonging survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research, Ethics Committee 02, United Kingdom, Favourable Opinion 9th October 2012, Ethics reference 12/SS/0144

Study design
Non-randomised open-label non-placebo controlled Phase IIb clinical trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact hifu@btconnect.com to request a patient information sheet or call 01865 763100 during office hours

Health condition(s) or problem(s) studied
Primary osseous malignant bone tumours of the sacrococcygeal spine such as chordoma, osteosarcoma, etc.

Interventions
The trial will take place at the Churchill Hospital, Oxford. All patients recruited must be referred from a tertiary health care doctor to be considered for the trial.
High Intensity focused ultrasound treatment (potentially staged treatment for large tumours)

under general anaesthetic. After treatment, patients can expect several appointments to check on the effect of treatment using clinical examination, MRI scans, blood tests and questionnaires.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
1. To evaluate the functional outcome, pain experience and survival of patients with sacral chordomas and other primary malignant bone tumours of the sacrum treated with HIFU
2. To evaluate the effect of HIFU on radiological progression of histologically proven chordomas and other primary malignant bone tumours of the sacrum

Secondary outcome measures
1. Volume of tumour ablation on day 42 (6 weeks) on MRI imaging expressed as a percentage of pre-treatment target tumour volume
2. Number and severity of AEs / toxicity following EC-HIFU based on CTC criteria; assessed at the following points:
C3 (day 1 post-HIFU)
C4 (day 2 post-HIFU)
C5 (day 42 post-HIFU)
C6 (Day 182 post-HIFU)
C7 (Day 365 post HIFU)
3. Evidence of cavitation during EC-HIFU expressed as a map of cavitation activity
4. Tumour volume at radiological follow-up; assessed at the following times:
C5 (6 weeks post-HIFU)
C8 (12 months post-HIFU)
5. Tumour uptake (if any) of intravenous contrast on digital-subtraction MRI imaging; assessed at the following times:
C5 (6 weeks post-HIFU)
C8 (12 months post-HIFU)

Overall study start date
01/05/2013

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 18 years or above
3. Lesions must be histologically verified as primary bone tumours of the spine either by prior radiologically-guided biopsy or by histological examination of prior surgically resected samples of the tumour
4. Participant must be in sufficiently good health to be suitable for general anaesthesia for both EC-HIFU treatment (generally ASA grade 1 or 2)
5. Subjects must have ≥ 1 evaluable tumours which can be visualised on diagnostic ultrasound. If

more than one tumour exists, an index tumour will be nominated and treated (uncommon)
6. Previous surgical resection and/or chemotherapy therapy for the primary bone tumour are permitted, but the subject should have recovered fully from the effects of these and the interventions should have been completed more than 12 months from the commencement of HIFU. Previous spinal fixation as part of the procedure to remove the original tumour will not be an exclusion criterion in itself, but if at the planning stage the fixation device interferes with treatment delivery, the patient may fail pre-assessment and be excluded from the trial
7. Patients should not have received radiotherapy to the target area within the preceding 12 months
8. Subject has clinically acceptable haematological, electrolyte and hepatic function as demonstrated by serum laboratory values within 14 days prior to EC-HIFU treatment:
8.1. Absolute neutrophil count (ANC) ≥ 1500mm-3
8.2. Platelet count ≥ 100,000mm-3
8.3. Haemoglobin ≥ 10gdl-1
8.4. Prothrombin time (PT) ≤ 1.5 * Upper Limit of Normal (ULN)
8.5. Activated partial thomboplastin time (APTT) ≤ 1.5 * ULN
8.6. Total bilirubin < 2.5 * ULN
8.7. Aspartate aminotransferase (AST) < 3 * ULN
8.8. Alkaline phosphatase (ALP) < 2 * ULN; unless arising from bone
9. Participants have a clinically acceptable ECG
10. Negative pregnancy test within 24 hours of EC-HIFU treatment (if appropriate)
11. Able (in the Investigators opinion) and willing to comply with all study requirements
12. Willing to allow his or her General Practitioner and referring Consultant, if appropriate, to be notified of participation in the study, and be contacted 5 years after treatment to assess survival
13. A World Health Organisation (WHO) performance status of ≤ 1

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Female participants who are pregnant, lactating or planning pregnancy during the course of the study (see pregnancy test note above)
2. Significant hepatic impairment
3. Significant renal impairment
4. Scheduled elective surgery or other procedures requiring general anaesthesia within a period of 8 weeks after finishing HIFU treatment
5. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participants ability to participate in the study.

6. Participants currently involved in any medicinal trial
7. Participants involved in the treatment phase of a clinical trial (observational or follow-up studies will be allowed)
8. If, during the planning stage, it is adjudged by the planning team that treatment to the tumour may pose an unacceptable risk to the patients life or health, for example if a segment of bowel is likely to be damaged by the HIFU beam, the patient will be excluded. In this circumstance the patients intention to participate in the trial will be recorded in the CRF and the technical reason for exclusion recorded. Patients excluded from the trial for technical reasons will be reported in future analyses to help scrutinising clinicians decide
on the viability of HIFU as a treatment.

Date of first enrolment
01/05/2013

Date of final enrolment
01/05/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Neurosurgery
Oxford
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Sponsor information

Organisation
Oxford University Hospitals NHS trust (UK)

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Sponsor type

Hospital/treatment centre

Website
http://www.ouh.nhs.uk/

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Oxford Biomedical Research Centre (UK) , Ref. A90104

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			27/08/2024	No	Yes