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A trial looking at whether stereotactic radiotherapy together with chemotherapy is a useful treatment for people with locally advanced bile duct cancer (ABC-07)

Submission date 14/10/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/10/2015	**Overall study status** Completed	
Last Edited 04/08/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/a-trial-looking-chemotherapy-stereotactic-radiotherapy-people-locally-advanced-bile-duct-cancer-abc-07

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2014-003656-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19234

Study information

Scientific Title
Addition of stereotactic body radiotherapy to systemic chemotherapy in locally advanced biliary tract cancers

Acronym
ABC-07

Study objectives
1. The overall aim of the feasibility component of the trial is to determine if it is feasible to deliver SBRT in a multi-centre trial setting in a rare disease
2. The overall aim of the phase II trial is to evaluate the efficacy of 8 cycles of CisGem chemotherapy compared to 6 of cycles of CisGem chemotherapy followed by SBRT

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Hampstead, 31/07/2015, ref: 15/LO/1077

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Biliary tract cancer

Interventions

Current interventions as of 19/07/2017:
All patients will be registered to receive 6 cycles of chemotherapy consisting of cisplatin 25 mg /m2 plus gemcitabine 1000 mg/m2 on days 1 and 8 of a 21-day cycle. Treatment takes about 2 hours each time.
Patients will then be randomised to one of two groups.

Investigational arm: Participants receive 5 or 15 fractions of SBRT over 5-21 days approximately 6 weeks after the start of cycle 6. (Number of fractions and duration of treatment depends on size of tumour on end of cycle 4 imaging).

Standard arm: Participants receive 2 further cycles of CisGem (8 cycles in total)

All patients will be followed up every 3 months for up to 2 years from date of registration.

Previous interventions:
All patients will be registered to receive 6 cycles of chemotherapy consisting of cisplatin 25 mg /m2 plus gemcitabine 1000 mg/m2 on days 1 and 8 of a 21-day cycle. Treatment takes about 2 hours each time.
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Intervention Type
Other

Primary outcome measure
Average monthly rate of recruitment is determined over the 18 month trial period.

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/07/2013

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/07/2017:
1. A histopathological/cytological diagnosis of locally advanced, non--resectable biliary tract carcinoma (intra- or extrahepatic), or ampullary carcinoma
2. Not suitable for radical surgery, or medically unfit for surgery as decided by a hepatobiliary MDT
3. Tumour visible on cross-sectional imaging

4. Measurable disease (according to RECIST criteria v1.1) (If disease is not measurable using RECIST v1.1, due to location in the vicinity of the hilum, the tumour must be visible for targeting with radiation using other multimodality imaging such as ERCP, MRCP)
5. Tumour (and nodes if involved) must be ≤12 cm in the longest dimension. For patients with non-measurable disease, sites should use the CT reconstructions (coronal or sagittal views) to measure tumour size.
6. Adequate biliary drainage
7. WHO performance status (PS) 0 or 1
8. Adequate haematological function:
8.1. Haemoglobin ≥ 100 g/L (the use of transfusion to achieve desired Hb is acceptable)
8.2. White blood cell count (WBC) ≥ 3.0 x 109/L
8.3. Absolute neutrophil count (ANC) ≥ 1.5 x 109/L
8.4. Platelet count ≥ 100 x 109/L
9. Adequate liver function:
9.1. Total bilirubin ≤ 1.5 x ULN (except for patients with known documented cases of Gilbert's syndrome)
9.2. ALT and/or AST ≤ 2.5 x ULN
9.3. ALP ≤ 5 x ULN
9.4. Albumin >25g/L
10. Adequate renal function:
10.1. Serum urea < 1.5 x ULN
10.2. Serum creatinine < 1.5 x ULN
10.3. GFR ≥ 45 mL/min using a validated creatinine clearance calculation (e.g. Cockroft-Gault or Wright formula). If the calculated creatinine clearance is less than 45 mL/min, GFR should be assessed using an isotopic clearance method to confirm GFR ≥ 45 mL/min
11. Life expectancy of more than 12 weeks
12. Aged 16 years or over
13. Patients may have had prior chemotherapy as long as patient meets all other inclusion /exclusion criteria
14. Patient must have given written informed consent

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Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 83; UK Sample Size: 83

Total final enrolment
83

Key exclusion criteria
Current exclusion criteria as of 19/07/2017:
1. Metastatic disease
2. Direct tumour extension in the duodenum, stomach, small bowel or large bowel.
3. Previous abdominal radiotherapy or previous selective internal radiotherapy such as hepatic arterial Yttrium therapy
4. Previous hypersensitivity to platinum salts
5. Any evidence of severe or uncontrolled systemic diseases which, in the view of the investigator, makes it undesirable for the patient to participate in the trial (including diabetes with established sensory peripheral neuropathy, unstable or uncompensated respiratory, cardiac, hepatic or renal disease)
6. History of prior malignancy that could interfere with the response evaluation or survival. (Exceptions include: in-situ carcinoma of the cervix treated by cone-biopsy/resection, non-metastatic basal and/or squamous cell carcinomas of the skin, or any early stage malignancy radically treated in the last two years, early prostate cancer under surveillance.
7. Other concomitant anti-cancer therapy (except steroids)
8. Any psychiatric or other disorder likely to impact on informed consent.
9. Women who are pregnant or lactating
10. Whilst not specifically excluded, patients with significant hearing impairment must be made aware of potential ototoxicity and may choose not to be included. If included, it is recommended that audiograms be carried out at baseline and prior cycle 2 of CisGem.

Previous exclusion criteria:
1. Metastatic disease

2. Direct tumour extension in the duodenum, stomach, small bowel or large bowel.
3. Previous abdominal radiotherapy or previous selective internal radiotherapy such as hepatic arterial Yttrium therapy
4. Previous hypersensitivity to platinum salts
5. Any evidence of severe or uncontrolled systemic diseases which, in the view of the investigator, makes it undesirable for the patient to participate in the trial (including diabetes with established sensory peripheral neuropathy, unstable or uncompensated respiratory, cardiac, hepatic or renal disease)
6. History of prior malignancy that could interfere with the response evaluation (exceptions include in-situ carcinoma of the cervix treated by cone-biopsy/resection, non-metastatic basal and/or squamous cell carcinomas of the skin, or any early stage (stage I) malignancy adequately resected for cure greater than 5 years previously)
7. Other concomitant anti-cancer therapy (except steroids)
8. Any psychiatric or other disorder likely to impact on informed consent.
9. Women who are pregnant or lactating
10. Whilst not specifically excluded, patients with significant hearing impairment must be made aware of potential ototoxicity and may choose not to be included. If included, it is recommended that audiograms be carried out at baseline and prior cycle 2 of CisGem.

Date of first enrolment
01/11/2015

Date of final enrolment
03/08/2022

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
University College Hospital
235 Euston Road
Fitzrovia
London

United Kingdom
NW1 2BU

Study participating centre
The Royal Marsden Hospital (Surrey)
Downs Road
Sutton
United Kingdom
SM2 5PT

Study participating centre
The Royal Marsden Hospital
Fulham Road
Chelsea
London
United Kingdom
SW3 6JJ

Study participating centre
Mount Vernon Cancer Centre
Rickmansworth Road
Northwood
United Kingdom
HA6 2RN

Study participating centre
Lister Hospital
Chelsea Bridge Road
London
United Kingdom
SG1 4AB

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff
United Kingdom
CF14 2TL

Study participating centre
St Bart's Hospital
W Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Hammersmith Hospital
Du Cane Road
White City
London
United Kingdom
W12 0HS

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way

Birmingham
United Kingdom
B15 2TH

Study participating centre
Christie Manchester
550 Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
Gower Street
London
England
United Kingdom
-

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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
We do not expect to make this data available to participants. The results will be published as soon as possible.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5.0	06/08/2020	17/11/2021	No	No
HRA research summary			28/06/2023	No	No