

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	☒ Prospectively registered ☒ Protocol
Registration date 14/10/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/01/2026	Condition category Cancer	☐ Individual participant data ☒ Record updated in last year

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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2014-003656-31

Protocol serial number

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

Primary study design

Interventional

Study design

Randomized; Interventional; Design type: Treatment

Study type(s)

Treatment

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.

Patients will then be randomised to one of two groups.

Investigational arm: Participants receive 5 fractions of SBRT over 5-15 days approximately 6 weeks after the start of cycle 6.

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Intervention Type

Other

Primary outcome(s)

Average monthly rate of recruitment is determined over the 18-month trial period

Key secondary outcome(s)

Not provided at time of registration

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) $\geq 3.0 \times 10^9/L$
 - 8.3. Absolute neutrophil count (ANC) $\geq 1.5 \times 10^9/L$
 - 8.4. Platelet count $\geq 100 \times 10^9/L$
9. Adequate liver function:
 - 9.1. Total bilirubin $\leq 1.5 \times ULN$ (except for patients with known documented cases of Gilbert's syndrome)
 - 9.2. ALT and/or AST $\leq 2.5 \times ULN$
 - 9.3. ALP $\leq 5 \times ULN$
 - 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 $\geq$ 45 mL/min using a validated creatinine clearance calculation (e.g. Cockcroft-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 $\geq$ 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

Previously inclusion criteria:

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)

5. Tumour must be $\leq$ 6 cm in the longest dimension

6. Adequate biliary drainage

7. WHO performance status (PS) 0 or 1

8. Adequate haematological function:

8.1. Haemoglobin $\geq$ 100 g/L (the use of transfusion to achieve desired Hb is acceptable)

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Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

16 Years

Upper age limit

100 Years

Sex

All

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

United Kingdom

England

Wales

Study participating centre

Churchill Hospital

Old Road
Headington
Oxford
England
OX3 7LE

Study participating centre

University College Hospital

235 Euston Road
Fitzrovia
London
England
NW1 2BU

Study participating centre

The Royal Marsden Hospital (Surrey)

Downs Road
Sutton
England
SM2 5PT

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

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

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

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

Study participating centre
Velindre Cancer Centre
Velindre Road
Cardiff
Wales
CF14 2TL

Study participating centre
St Bart's Hospital
W Smithfield

London
England
EC1A 7BE

Study participating centre

Hammersmith Hospital

Du Cane Road
White City
London
England
W12 0HS

Study participating centre

Southampton General Hospital

Tremona Road
Southampton
England
SO16 6YD

Study participating centre

Addenbrooke's Hospital

Hills Road
Cambridge
England
CB2 0QQ

Study participating centre

Queen Elizabeth Hospital

Mindelsohn Way
Birmingham
England
B15 2TH

Study participating centre

Christie Manchester

550 Wilmslow Road
Manchester
England
M20 4BX

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
England
NG5 1PB

Sponsor information

Organisation
University College London

ROR
<https://ror.org/02jx3x895>

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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?
HRA research summary			28/06/2023	No	No
Other publications	Radiotherapy quality assurance	04/12/2025	12/01/2026	Yes	No
Protocol file	version 5.0	06/08/2020	17/11/2021	No	No