ISRCTN10639376 https://doi.org/10.1186/ISRCTN10639376

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

Registration date
14/10/2015

Overall study status
Completed

Last Edited
17/08/2026

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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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
Ethics approval required

Ethics approval(s)
Approved 04/08/2015, London - Hampstead Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8284; hampstead.rec@hra.nhs.uk), 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:
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Intervention Type
Other

Primary outcome(s)
Current primary outcome as of 17/08/2026:
The efficacy of 6 cycles of CisGem followed by SBRT versus 8 cycles of CisGem, measured using progression-free survival (PFS), assessed from randomisation to disease progression (RECIST v1. 1 on CT/MRI) or death from any cause.

Previous primary outcome:
Average monthly rate of recruitment is determined over the 18-month trial period

Key secondary outcome(s)
Added 17/08/2026:
1. Progression-free survival (PFS) measured using CT and/or MRI imaging assessments (RECIST v1.1) and death from any cause, at 9 months from randomisation
2. The frequency and severity of toxicities measured using CTCAE v4.03 at registration, all treatment visits, completion of treatment, and all follow up visits.
3. Best overall response will be assessed according to RECIST v1.1. Confirmation of a complete or partial response is not required. Stable disease will be considered the best response only if a second assessment has been carried out which confirms SD at least 4 weeks after registration. The proportion of patients whose best overall response is complete or partial will be presented.
4. The duration of overall response is measured from the time of best overall response until the date of objective disease progression on CT and/or MRI.
5. Sites of treatment failure measured using CT and/or MRI assessment of local progression, regional progression and distant metastases according to protocol-defined radiological criteria, at all scheduled follow-up visits from treatment completion.
6. The potential for CisGem + SBRT to downstage inoperable disease to operable disease, measured using the proportion of patients achieving downstaging permitting surgical resection, at treatment completion.
7. Overall survival measured from the date of randomisation to the date of death from any cause. The effect of treatment on overall survival will be summarised using Kaplan-Meier curves. Cox regression will be used to assess the effect of treatment on overall survival, and hazard ratios, 95% confidence interval and p-values will be reported.
8. Quality of life (QoL) measured using the EQ5D and EORTC QLQ- BIL21 questionnaires. Analysis of covariance will be used to assess treatment differences in the quality of life scores at completion of treatment and at 3 months follow-up, adjusting for baseline scores (registration and end of cycle 4).

Completion date
12/08/2026

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

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

Scotland

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

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
Scotland
G12 0YN

Study participating centre
Bristol Haematology & Oncology Centre
Horfield Road
Bristol
England
BS2 8ED

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
England
SE1 9RT

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Weston Park Hospital
Whitham Road
Sheffield
England
S10 2SJ

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
Protocol file	version 7.0	01/05/2024	17/08/2026	No	No