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Clinical registry of cancers of the biliary tract

Submission date 26/08/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/09/2020	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 27/12/2023	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Biliary Tract Cancers (BTC) are tumours arising from the lining of bile ducts. The subtypes of BTCs have similarities but also important differences that can affect their clinical behaviour. The incidence of BTC is increasing all around the world with regional differences in the distribution of subtypes according to risk factors. The aim of this study is to collect clinical data from patients with a diagnosis of BTC in order to define the characteristics and the overall survival in this population.

Who can participate?
Patients aged over 18 years old with a diagnosis of BTC from 2020 to 2024

What does the study involve?
The study involves collecting clinical information on the course of the disease and the response to different treatments. There is an optional choice to provide a number of blood, urine, bile and tissue samples for the duration of treatment and follow-up.

What are the possible benefits and risks of participating?
There are no specific risks or benefits to participants.

Where is the study run from?
Beatson West of Scotland Cancer Centre (UK)

When is the study starting and how long is it expected to run for?
October 2019 to December 2030

Who is funding the study?
University of Glasgow (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
276732

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 276732

Study information

Scientific Title
REGBil: Clinical REGistry and molecular characterisation of Biliary tract cancers

Acronym
Reg-Bil

Study objectives
To study overall survival in patients with biliary tract cancers in a prospective fashion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/07/2020, South West - Frenchay Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol. BS1 2NT; UK; +44 (0)207 1048028; frenchay.rec@hra.nhs.uk), ref: 20/SW/0054

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Biliary tract cancers

Interventions
At study entry, patients will be asked to give their consent for the team to collect their clinical information on the course of their disease. They will also be asked to provide blood, urine, bile and tissue samples for development of markers of response to drug therapy and generation of mini-tumours in the lab. These samples will be collected over the treatment and potentially up to 5 years from study entry.

Intervention Type
Other

Primary outcome measure
Overall survival (OS) collected from patient notes up to 5 years from time of diagnosis

Secondary outcome measures
Collected from patient notes up to 5 years from time of diagnosis:
1. Disease-free survival (DFS) in patients undergoing radical surgery
2. Chemotherapy outcomes with each line of therapy (response rate, progression-free survival)
3. Proportion, DFS, and OS of subtypes of biliary tract cancers
4. DFS and OS according to subgroups (grouped in intrahepatic and extrahepatic BTC)

Exploratory outcome measures:
1. Feasibility of organoids generation from BTC assessed using fresh tumour tissue at baseline and at time of progression
2. Presence and absolute quantities of circulating DNA, circulating microRNA and other relevant biomarkers measured using digital PCR, every 3 months during the course of treatment and at progression
3. Circulating DNA in bile measured using sequencing technologies at baseline
4. Potential biomarkers of BTC measured using sequencing at baseline
5. Circulating and tissue based biomarkers in BTC measured using metabolomics and proteomic approaches every 3 months during the course of treatment and progression

Overall study start date
01/10/2019

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Patients with radiological or cytological/histological diagnosis of BTC, who have been diagnosed and/or treated at NHS Greater Glasgow and Clyde
3. Informed written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Medical or psychiatric conditions impairing ability to give informed consent

Date of first enrolment
01/09/2020

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde

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Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR

https://ror.org/05kdz4d87

Funder(s)

Funder type
University/education

Funder Name
University of Glasgow

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/3031

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No