

# Clinical registry of cancers of the biliary tract

<b>Submission date</b> 26/08/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/09/2020	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/12/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

1. Dr Chiara Braconi, [chiara.braconi@glasgow.ac.uk](mailto:chiara.braconi@glasgow.ac.uk)
2. Karen Allan, [karen.allan.3@glasgow.ac.uk](mailto:karen.allan.3@glasgow.ac.uk)

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Chiara Braconi

**ORCID ID**

<http://orcid.org/0000-0003-4835-1259>

**Contact details**

Beatson West of Scotland Cancer Centre  
1053 Great Western Road  
Glasgow  
United Kingdom  
G12 0YN  
+44 (0)141 330 3278  
[chiara.braconi@glasgow.ac.uk](mailto:chiara.braconi@glasgow.ac.uk)

**Type(s)**

Public

**Contact name**

Ms Karen Allan

**Contact details**

Glasgow Oncology Clinical Trials Unit (GO CTU)  
Partner in CaCTUS - Cancer Clinical Trials Unit Scotland  
Level 0  
Beatson West of Scotland Cancer Centre  
Gartnavel General Hospital  
Glasgow  
United Kingdom  
G12 0YN  
+44 (0)141 301 7959 (internal 57959)  
[karen.allan.3@glasgow.ac.uk](mailto:karen.allan.3@glasgow.ac.uk)

**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

Glasgow

United Kingdom

G12 0YN

**Sponsor information****Organisation**

NHS Greater Glasgow and Clyde

**Sponsor details**

Dykebar Hospital

Grahamston Road

Paisley

Scotland

United Kingdom

PA2 7DE

+44 (0)141 301 9917

joanne.mcgarra@ggc.scot.nhs.uk

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No