# A Randomised trial of Adjuvant Chemotherapy (ECF) in Biliary Cancer

Submission date Recruitment status Prospectively registered 19/08/2002 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 19/08/2002 Completed [X] Results Individual participant data **Last Edited** Condition category 26/03/2020 Cancer

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** RMH E/C 1325

# Study information

#### Scientific Title

A Randomised trial of Adjuvant Chemotherapy (ECF) in Biliary Cancer

#### **Study objectives**

Not provided at time of registration

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Biliary tract cancer

#### **Interventions**

Two Arms:

1. ECF - 5-Fluorouracil (5FU) 200 mg/m2 continuous infusion daily Epirubicin 50 mg/m2 3 weekly IV bolus Cisplatin 60 mg/m2 3 weekly

2. No treatment

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Not provided at time of registration

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/01/2000

#### Completion date

28/02/2002

# **Eligibility**

#### Key inclusion criteria

- 1. Histological confirmed carcinoma of biliary tract or gall bladder
- 2. Disease considered to have been completely resected
- 3. No metastases on staging

#### Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### Target number of participants

Not provided at time of registration

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/01/2000

#### Date of final enrolment

28/02/2002

## Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre UKCCCR Register Co-ordinator

London United Kingdom NW1 2DA

# Sponsor information

#### Organisation

Royal Marsden Hospital (UK)

#### Sponsor details

Downs Road Sutton England United Kingdom SM2 5PT +44 (0)20 8661 3156 david.cunningham@rmh.nhs.uk

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/034vb5t35

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Royal Marsden Hospital (UK)

### **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Results article results 01/09/1995 26/03/2020 Yes No