A randomised trial comparing epirubicin, cisplatin and protracted venous infusion (PVI) 5-Fluorouracil (5FU) (ECF) to 5FU, Etoposide Leucovorin (FELU) in patients with inoperable or metastatic biliary cancer

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/08/2002		☐ Protocol		
Registration date 19/08/2002	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
19/02/2014	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 +44 (0) 20 7670 4723

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RMH E/C 1323

Study information

Scientific Title

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Biliary Tract

Interventions

1. FELU: 5FU 600 mg/m2 IV bolus 1-3 every 3 weeks Etoposide 120 mg/m2 IV infusion over 40 min days 1-3 every 3 weeks Leucovorin 60 mg/m2 IV bolus days 1-3 every 3 weeks 2. ECF: 5FU 200 mg/m2 daily continuous infusion for 24 weeks. Epirubicin 50 mg/m2 3-weekly IV bolus Cisplatin 60 mg/m2 3 weekly

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cancer drugs

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

31/12/2005

Eligibility

Key inclusion criteria

- 1. Histological locally advanced or metastatic adenocarcinoma, squamous carcinoma or undifferentiated carcinoma of the gallbladder, intra/extra-hepatic bile ducts or Ampulla of Vater
- 2. Measurable disease on Computed Tomography (CT), Magnetic Resonance Imaging (MRI) or radiograph

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

31/12/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre UKCCCR

London United Kingdom NW1 2DA

Sponsor information

Organisation

The Royal Marsden NHS Foundation Trust (UK)

Sponsor details

Downs Road Sutton England United Kingdom SM2 5PT

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/0008wzh48

Funder(s)

Funder type

Research organisation

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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/05/2005		Yes	No