ISRCTN73941125 https://doi.org/10.1186/ISRCTN73941125

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 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 19/02/2014	**Condition category** 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 summary

Not 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