

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/02/2014	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

UKCCCR

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

The Royal Marsden NHS Foundation Trust (UK)

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Research organisation

Funder Name

Royal Marsden Hospital (UK)

Results and Publications

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