

Phase II randomized trial comparing 5-fluorouracil in continuous infusion and cisplatin (FP) versus leucovorin, bolus 5-fluorouracil and cisplatin (FLP) in metastatic gastric, pancreatic and oesophageal cancer

Submission date 01/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/09/2009	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Marc Ychou

Contact details
CRLC Val d'Aurelle
Parc Euromédecine
Montpellier
France
34298
MYchou@valdorel.fnclcc.fr

Additional identifiers

Protocol serial number
FFCD 9404 trial

Study information

Scientific Title**Acronym**

FFCD 9404

Study objectives

Compare the safety (primary objective) and clinical efficacy and quality of life (secondary objectives) of FLP versus FP as a first line chemotherapy in patients with metastatic gastric, pancreatic and oesophageal cancer

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Metastatic gastric, pancreatic and oesophageal cancer

Interventions

First line chemotherapy - 5-fluorouracil in continuous infusion and cisplatin (FP) versus leucovorin, bolus 5-fluorouracil and cisplatin (FLP)

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

5-fluorouracil and cisplatin (FP) and leucovorin, bolus 5-fluorouracil and cisplatin (FLP)

Primary outcome(s)

Safety

Key secondary outcome(s)

Clinical efficacy and quality of life

Completion date

01/05/1997

Eligibility

Key inclusion criteria

Histologically proven carcinoma of the oesophagus, the stomach or the pancreas, with a measurable metastatic disease (≤ 15 mm) and without indication of radiotherapy and/or surgery; no prior chemotherapy for metastatic disease and, in case of adjuvant chemotherapy, no regimen containing cisplatin; age ≤ 75 years and World Health Organization (WHO) performance status < 2 ; adequate baseline organ function, defined as neutrophil count $\geq 1500/\text{mm}^3$, platelet count $\geq 100,000/\text{mm}^3$ and creatinine level < 1.25 normal level; in case of patient older than 70 years and/or creatinine level between 1 and 1.25 normal limit, creatinine clearance had to be more than 60 ml/min; and written informed consent approved by the local Ethical Committee was given by all the participants before they entered the study.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Severe uncontrolled co-morbidities, brain metastases

Date of first enrolment

01/04/1995

Date of final enrolment

01/05/1997

Locations

Countries of recruitment

France

Study participating centre

CRLC Val d'Aurelle

Montpellier

France

34298

Sponsor information

Organisation

French Federation of Digestive Cancers (Fédération Francophone de la Cancérologie Digestive [FFCD]) (France)

ROR

<https://ror.org/02q7qcb13>

Funder(s)

Funder type

Industry

Funder Name

Lederle F93/LFOL/02

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	01/09/2006		Yes	No