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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/09/2005	**Overall study status** Completed	
Last Edited 24/09/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Safety

Secondary outcome measures
Clinical efficacy and quality of life

Overall study start date
01/04/1995

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 neutrophile count ≥1500/mm^3, platelet count ≥100,000/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/mm; 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

Age group
Adult

Sex
Both

Target number of participants
232

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)

Sponsor details
7 bd Jeanne d'Arc
Dijon
France
21033
obouche@chu-reims.fr

Sponsor type
Other

Website
http://www.ffcd.fr/

ROR
https://ror.org/02q7qcb13

Funder(s)

Funder type
Industry

Funder Name
Lederle F93/LFOL/02

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	01/09/2006		Yes	No