

# 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

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|--|---|---|
| <b>Submission date</b><br>01/09/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>06/09/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>24/09/2009       | <b>Condition category</b><br>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

**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 ( $\leq 15$  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  $\leq 75$  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

**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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/09/2006   |            | Yes            | No              |