

A phase III trial of postoperative cisplatin, interferon alpha-2b, and 5-FU combined with external radiation treatment versus 5-FU alone for patients with resected pancreatic adenocarcinoma

Submission date 23/11/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 16/02/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/10/2016	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Pancreatic cancer is cancer that starts in the pancreas (a gland that produces digestive juices and hormones). It can be treated with surgery to remove the cancer, followed by chemotherapy, where anti-cancer medicines are used to kill any cancerous cells left behind (adjuvant chemotherapy). This lowers the risk of the cancer coming back and prolongs patient survival, but its benefit is limited. Chemoradioimmunotherapy is a combination of chemotherapy, radiotherapy (which uses high energy rays to kill cancer cells) and immunotherapy (treatment that re-awakens the immune system so it can fight cancer). The aim of this study is to assess the effect of chemoradioimmunotherapy compared with adjuvant chemotherapy alone.

Who can participate?

Patients aged over 18 who have undergone surgery to completely remove pancreatic cancer within the last 12 weeks

What does the study involve?

Participants are randomly allocated to be treated with either chemoradioimmunotherapy (fluorouracil, cisplatin and interferon alfa-2b plus radiotherapy followed by two cycles of fluorouracil), or six cycles of adjuvant chemotherapy (fluorouracil). Patient survival is assessed two years later.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part, but there should be benefits to future patients with pancreatic cancer because the results of the study are likely to influence treatment. The main risk of the study will be side effects of the treatment. The participants will be closely monitored on a daily/weekly basis.

Where is the study run from?

The study has been set up by the University of Heidelberg in collaboration with various clinics in Germany and the Department of General and Oncological Surgery, Ospedale Mauriziano "Umberto I", Torino, Italy.

When is the study starting and how long is it expected to run for?

August 2004 to July 2006

Who is funding the study?

Manfred-Lautenschläger-Foundation (Germany)

Who is the main contact?

Prof. Dr med. M. W. Büchler

markus.buechler@med.uni-heidelberg.de

Contact information

Type(s)

Scientific

Contact name

Prof Markus Büchler

Contact details

Im Neuenheimer Feld 110

Heidelberg

Germany

69120

+49 (0)6221 56 6201

markus.buechler@med.uni-heidelberg.de

Additional identifiers

Protocol serial number

L-042/2003

Study information

Scientific Title

A phase III trial of postoperative cisplatin, interferon alpha-2b, and 5-FU combined with external radiation treatment versus 5-FU alone for patients with resected pancreatic adenocarcinoma

Acronym

CapRI

Study objectives

The aim of this study is to evaluate the overall survival period attained by chemo-radiotherapy including interferon alpha-2b administration with adjuvant chemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the University of Heidelberg Medical School, ref: L-042/2003

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pancreatic cancer

Interventions

Patients in study arm A will be treated with:

1. 200 mg/m²/day 5-Fluorouracil (5-FU) by continuous intravenous (IV) infusion on days 1 - 38
2. 30 mg/m² Cisplatin IV over 60 minutes (with pre- and post-hydration) on days 1, 8, 15, 22, 29, 36 (6 doses)
3. 3 million units subcutaneous (SC) Interferon alpha-2b days 1 - 38 (17 total doses)

External beam radiation is to be given concurrently with chemotherapy with a total dose of 50.4 Gy in 28 fractions over 5.5 weeks (1.8 Gy/day).

In study arm A the patients receive post-chemoradiation 5-FU infusions of 200/mg/m²/day by continuous intravenous infusion on days 64 - 101 and 120 - 161.

Patients in study arm B will be treated with 20 mg/m² intravenous bolus injection of Folinic acid, D-L form, followed by 425 mg/m²/day intravenous bolus injection of 5-FU given on 5 consecutive days every 28 days for 6 cycles i.e. 24 weeks.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Cisplatin, interferon alpha-2b, 5-fluorouracil (5-FU)

Primary outcome(s)

Overall survival at two years postoperatively

Key secondary outcome(s))

1. Role and the mechanism of interferon alpha-2b in patient's chemoradiation regimen
2. Toxicity
3. Disease-free interval
4. Quality of life

Completion date

31/07/2006

Eligibility

Key inclusion criteria

1. Biopsy proven completely resected (R0 or R1) pancreatic adenocarcinoma of the pancreatic head or uncinate process (American Joint Committee on Cancer [AJCC] Stage I-III)
2. Protocol treatment must begin within 12 weeks of surgery
3. Men and women over eighteen years of age

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not comply with above inclusion criteria

Date of first enrolment

01/08/2004

Date of final enrolment

31/07/2006

Locations

Countries of recruitment

Germany

Study participating centre

Im Neuenheimer Feld 110

Heidelberg

Germany

69120

Sponsor information

Organisation

University of Heidelberg (Germany)

ROR

<https://ror.org/038t36y30>

Funder(s)**Funder type**

Research organisation

Funder Name

Manfred-Lautenschlager-Foundation, Gaiberg (Germany)

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	20/11/2012		Yes	No
Protocol article	protocol	12/04/2005		Yes	No
Abstract results	abstract LBA4012	20/06/2010		No	No
Other publications	report on several cases	10/05/2006		Yes	No