ISRCTN62866759 https://doi.org/10.1186/ISRCTN62866759

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

Registration date
16/02/2005

Overall study status
Completed

Last Edited
18/10/2016

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pancreatic cancer

Interventions
Patients in study arm A will be treated with:
1. 200 mg/m^2/day 5-Fluorouracil (5-FU) by continuous intravenous (IV) infusion on days 1 - 38
2. 30 mg/m^2 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/m^2/day by continuous intravenous infusion on days 64 - 101 and 120 - 161.

Patients in study arm B will be treated with 20 mg/m^2 intravenous bolus injection of Folinic acid, D-L form, followed by 425 mg/m^2/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 measure
Overall survival at two years postoperatively

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

Overall study start date
01/08/2004

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

Age group
Adult

Sex
Both

Target number of participants
110

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)

Sponsor details
Im Neuenheimer Feld 110
Heidelberg
Germany
69120

Sponsor type
University/education

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
Research organisation

Funder Name
Manfred-Lautenschlager-Foundation, Gaiberg (Germany)

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