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Extended versus standard lymphadenectomy in patients undergoing pancreaticoduodenectomy for periampullary adenocarcinoma

Submission date
26/10/2014

Recruitment status
No longer recruiting

Registration date
07/11/2014

Overall study status
Completed

Last Edited
07/11/2014

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pancreaticoduodenectomy, otherwise known as the Whipple procedure, is the curative treatment of choice for periampullary adenocarcinoma, a cancer of an enlarged duct that connects the ducts of the liver and pancreas to the small intestine. The prognosis for the patients that have had the surgery is generally poor, however, with a 5 year survival rate ranging between 7-34%. Various efforts have been made to improve this. The size of the tumor, the degree of tumor differentiation (how much the tumor tissue resembles normal tissue), the use of adjuvant chemotherapy (chemotherapy given to destroy cancer cells that may still be present after a tumor has been removed by surgery) and how much it has spread are all important factors affecting a patients prognosis. Here, we want to compare how effective one type of surgical treatment, pancreaticoduodenectomy with radical extended lymphadenectomy (ELA) is compared to pancreaticoduodenectomy with standard lymphadenectomy (SLA) is in treating patients with periampullary adenocarcinoma.

Who can participate?
Adult patients that have been diagnosed with, or are suspected to have, a periampullary adenocarcinoma.

What does the study involve?
All participants have their duodenum (small intestine) and pancreatic head (part of the pancreas closest to the duodenum) removed during surgery. They are then randomly allocated into one of two groups. Those in group 1 undergo SLA. Those in group 2 undergo ELA. All patients receive a special check-up with CT scan 9 and 18 months after surgery to check for the appearance of more tumors.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. The offered surgical procedure is a standard procedure. The 50 patients undergoing ELA have a higher risk for ascites (build-up of fluid in the abdomen) and lymph fistula (leaking of lymph fluid) after surgery. Participants undergoing ELA may be less likely to develop further tumors.

Where is the study run from?
University of Saarland (Germany)

When is the study starting and how long is it expected to run for?
January 2006 to December 2011

Who is funding the study?
University of Saarland (Germany)

Who is the main contact?
Professor Otto Kollmar
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
190/05

Study information

Scientific Title
Extended versus standard lymphadenectomy in patients undergoing pancreaticoduodenectomy for periampullary adenocarcinoma a prospective randomized single center trial

Acronym
SLA-ELA

Study objectives

In the literature, former randomized studies investigating extended lymphadenectomy (ELA) versus standard lymphadenectomy (SLA) failed to show an overall benefit by the radical approach. However, these studies used different and therefore not comparable protocols for SLA. Therefore, the present randomized prospective single center trial uses a standardized protocol for SLA. The aim of the present single center trial is to evaluate whether ELA is capable of improving local progression free survival compared to standardized SLA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical review committee of the Saarland University, Homburg/Saar Germany (Identification number: 190/05).

Study design
Randomized single center trial comparing two arms of lymphadenectomy.

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pancreatic cancer: periampullary adenocarcinoma, including tumors of the pancreatic head, the distal common bile duct and the ampulla of Vater

Interventions
Surgery: Patients underwent pancreaticoduodenectomy with standard (SLA) or Extended (ELA) lymphadenectomy. SLA is defined as lymphadenectomy of the anterior and posterior lymph nodes of the pancreatic head, the supra- and infrapyloric lymph nodes and lymph nodes along the common hepatic artery. In accordance with the lymph node classification of the Japanese Gastric Cancer Society, SLA includes the lymph node levels 5, 6, 8a/p, 12a, 13 and 17. ELA includes all lymph node levels of SLA enlarged by all lymph nodes along the hepatoduodenal ligament, the coeliac trunk, the interaortocaval lymph nodes and the lymph nodes along the superior mesenteric artery. According to the Japanese Gastric Cancer Society ELA matches the lymph node levels of SLA plus the lymph node levels 9, 12p/b, 14a-v and 16a1, 16a2, 16b1.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Local progression free survival. Directly after 9 and 18 months, a CT scan is performed. With this CT scan any local recurrence of the tumour and distant metastases can be detected.

Secondary outcome measures
1. Overall survival
2. Morbidity

Overall study start date
09/01/2006

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Patients with confirmed diagnosis or suspicion of a periampullary adenocarcinoma, including tumors of the pancreatic head, the distal common bile duct and the ampulla of Vater.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120, 60 patients in each arm

Key exclusion criteria
1. Age <18 years and metastatic disease
2. Unresectability of the tumor
3. Absence of malignancy in the final histology

Date of first enrolment
09/01/2006

Date of final enrolment
31/12/2011

Locations

Countries of recruitment

Germany

Study participating centre
Robert-Koch-Strasse 40
Götingen
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D-37075

Sponsor information

Organisation
University of Saarland (Germany)

Sponsor details
Kirrbergerstrasse
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Sponsor type
University/education

ROR
https://ror.org/01jdpyv68

Funder(s)

Funder type
University/education

Funder Name
University of Saarland, Homburg/Saar (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