Patient information

Distal Pancreatectomy – A randomised controlled Trial to compare two different surgical techniques

DISPACT - Trial

Dear Patient,

You have been admitted to our hospital for treatment of a pancreatic disease, which needs to be operated. The aim of the operation is to remove the affected part of the organ, the so called *pancreatic tail*. We would like to invite you to take part in a clinical study, which compares the two most commonly used surgical techniques to remove the pancreatic tail.

The planned operation can result in a number of complications of which your doctor will inform you about. In addition to wound infections, vascular or nerve damage, the so-called pancreatic fistula is a common complication. This can require a further operation or additional procedures such as interventional drainage.

What is the aim of this study?

The aim of this study is to determine which operative technique results in the lowest risk for one of the most common complication – namely pancreatic fistula. Therefore this study compares two surgical methods. Both these operations remove the diseased section of the pancreas, the pancreatic tail. This partial resection of the organ can be carried out with the traditional scalpel or with a machine cutter (stapler). In case of the stapler-technique, the remaining pancreas is closed by a staple line, whereas hand sutures are used, when the scalpel resection is done. Both techniques are standard surgical techniques which are often used. But until now it has not been clearly shown which one of these techniques has the lowest risk for the occurrence of the so-called pancreatic fistula.

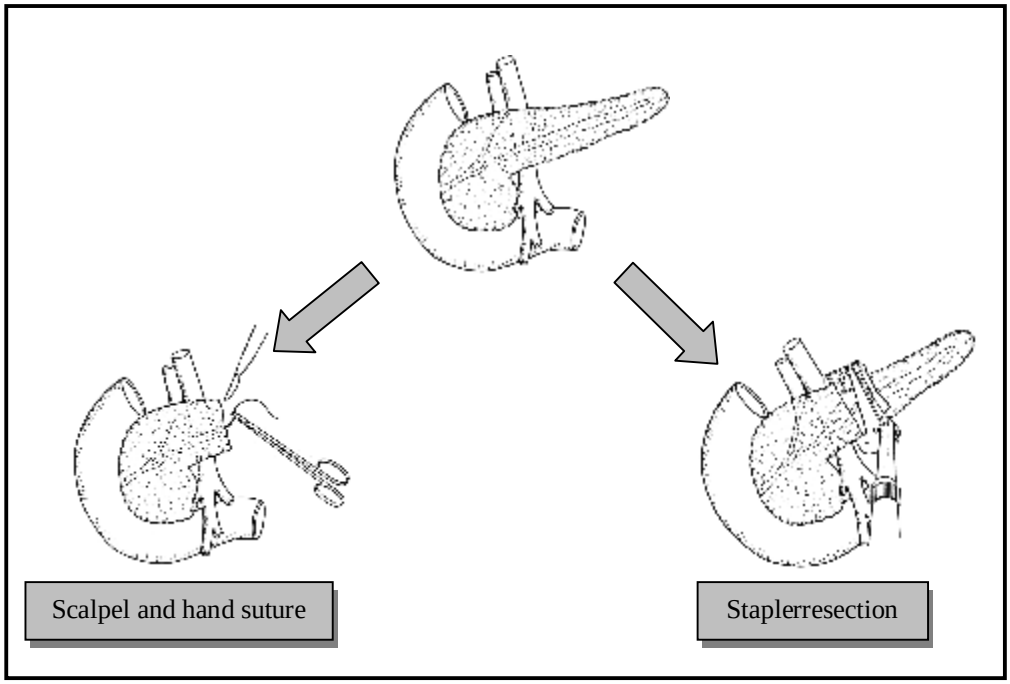

Figure 1: Pancreatic left resection and management of the pancreatic remnant

Benefit-Risk-Ratio

The above mentioned techniques represent the two standard surgical procedures for resections of the pancreatic tail. Currently it is unclear which of these procedures is better. Therefore it is impossible to say whether one method bears advantages or disadvantages in comparison with the other technique. With your participation in this clinical trial you will help in finding the best clinical method for future patients having to undergo such a resection.

What happens to me in case of participation?

The allocation to one of the treatment groups will be done by randomization before the operation. This means that chance decides into which group you are selected. This random assignment can not be foreseen or influenced by the surgeon guaranteeing high scientific value of the trial.

StudyVisits

After the operation, staff from our study team will closely follow your postoperative course. On these three postoperative visits, we will measure the amount of fluid in your surgical drains, in order to allow early detection of a pancreatic fistula. Additionally we will document any further side effects of your medication or resulting from surgery. No additional blood examinations or invasive investigations are necessary for this study. The required blood samples will be obtained within the routine postoperative blood tests.

Follow-up

Thirty days after the operation, you will be asked about your recovery and about complications or side-effects by telephone. After 12 months, you will be asked again about you current well-being.

Voluntary participation, premature withdrawal and data protection

Participation in this study is by free will. You can withdraw your consent at any time, without justification of the reasons. No disadvantages in regard to your medical treatment will result from your withdrawal. All required data will be pseudonymously documented and analyzed. To audit the plausibility of the data, insight into your patients' chart will be necessary. Therefore you will be asked to authorize members of the study committee to inspect your personal patient documents. Naturally, all participating persons are obligated to handle your data discretely and are not allowed to give them to third parties not involved in this study. .

Any questions?

If you have any further questions regarding your disease, your treatment or the this study, do not hesitate to get in contact with your doctor. All your questions will be answered in detail.

Clinical Investigator: _____

Telephone Clincal Inv.: _____

Telephone Study Nurse: _____

Responsible Principle Investigator:
Prof. M.W. Büchler
Telephone +49-6221-56-6200
Fax +49-6221-56-5450
Email Markus_Buechler@med.uni-heidelberg.de

Thank you for your participation · **This document is for the records**

Distal Pancreatectomy – A randomised controlled Trial to compare two different surgical techniques

Informed consent

I have been fully informed about the purpose, meaning and course of this study as well as any additional strains or risks associated with the study as stated in the patient information document, of which I received a copy and I was also consulted by _____ . Therefore all questions have been sufficiently answered.

I freely agree to take part in the above mentioned study. I know that I can at all times opt out of this study.

I have been informed and agree to that in the course of this study my personal information will be documented pseudonymously and that third persons will be allowed looking at the original documents for confirmation purposes. In case of withdrawal of my informed consent I agree with the analysis of already collected data (Please indicate below if applicable):

O YES O NO.

_____ _____

Name, Surname study patient (printed characters) | Date of birth

_____ _____

Signature study patient | Date of informed consent (inserted by patient)

_____

Name, Surname clinical investigator (printed characters)

_____ _____

Signature clinical investigator | Date of informed consent (inserted by clinical investigator)