Study Centre of the German
Surgical Society (SDGC)

ChroPac

Newsletter 1 / 2009

Topics

Editorial

Dear members of the ChroPac-study group,

After the successful trial meeting in May we would like to thank all participants for attending so numerously and playing an active role at the meeting. We are glad 27 colleagues were able to join our meeting. We've been listening to some very interesting lectures and enjoyed the exchange of experiences a lot. Analysis of our evaluation sheets showed, that nearly all members assessed content, comprehension and learning effect of the meeting excellent or very good. Particularly the surgical training was very much appreciated.

ChroPac Meeting May, 14th and 15th 2009

1. row: Stefan Kißenkötter, Jens Werner, Jan Schmidt, Christoph Seiler, Jens Werner, Tobias Keck
2. row: Ulrich Steger, Maria Lechner, Sabine Boas-Knoop, Olivia Sick, Sven Jonas, Marco Niedergethmann, Monika Janot, Seema Chauhan, Kathrin Grummich
3. row: Birgit Saliev, Bernhard Renz, Matthias Glanemann, Axel Kleespies, Snjažana Jeremič, Kerstin Pieper
4. row: Inga Wegener, Dagmar Anders, Hans-Michael Hau, Inga Rossion, Chris Halloran, Aleš Tomažic

With this newsletter we would like to inform you about current ethics and contract procedures.

First we want to introduce our new colleague Dr. Claudia Bauer to you. She is a dentist from the Ludwig-Maximilians- University of Munich where she has gained some years of experience as a research assistant as well as in students training.
From now on, she will be in charge of the ChroPac–study as a trial coordinator at the SDGC. Don't hesitate to contact her under claudiam.bauer@med.uni-heidelberg.de, if any questions arise.

We are happy to inform you that the ChroPac trial has already recruited 4 patients.

Christoph M. Seiler, MD

Participating centres

In total 13 centres will participate in the ChroPac trial: Amsterdam, Berlin, Bochum, Freiburg, Heidelberg, Leipzig, Liverpool, Ljubljana, Mannheim, München (LMU and TU), Regensburg and Würzburg. So far, six ethics approvals have been obtained (Berlin, Freiburg, Heidelberg, Leipzig, Mannheim, Würzburg), so that these centres can soon be initiated. After Heidelberg being the first centre initiated, Mannheim followed on September,1st. We would sincerely like to ask all of you to sign and return the contracts quickly, so that all centres will have randomized at least 1 patient by the end of the year. Furthermore we beg all centres which have not submitted an ethics application yet to do so soon.

Shipment of study documents

Contract

Research contracts for scientific cooperation between the two partners SDGC and participating centre are being sent out via e-mail attachment. Please make four print-outs. We need all four copies back, dated and signed by the head of the department and your institution's chief executive officer, so our administration can sign the contract as well.
Please determine a project manager and give bank details for case payment which is € 1.500 / patient.

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Ethics procedure

The following documents are commonly required for ethics approval:

1. application form of local ethics committee
2. trial protocol
3. patient information and informed consent forms
4. primary ethics vote (IEC of principal investigator)
5. names of responsible investigators on site
6. CV of local investigators

If you like, the SDGC will assist you with the ethics procedure.

Requirement for initiation

Before initiation ethics approval, signed contract, signed trial protocol, patient information – informed consent form, MACRO access and Randomizer.at registration have to be on hand.

If all these conditions are fulfilled please make an appointment with our responsible monitor Daniela Jackson from the KKS-Heidelberg (coordinating centre for clinical trials) by phone: 06221- 56 36909 or e-mail Daniela.Jackson@med.uni-heidelberg.de.

On the day of initiation you need the following equipment :

- Computer with internet access
- Updated CV of principal investigator (dated and signed), CV of other investigators can be filed later in the ISF (Investigator Site File)
- Connection of Randomizer. at :
    - E-Mail addresses of investigators authorised for randomisation

At initiation visit everybody involved in the trial should be present :

Principal investigator, investigator, study nurse

Relevant trial documents, such as ISF and CRF, will be brought with the monitor. If there are any questions the monitor will help to clarify them with you.

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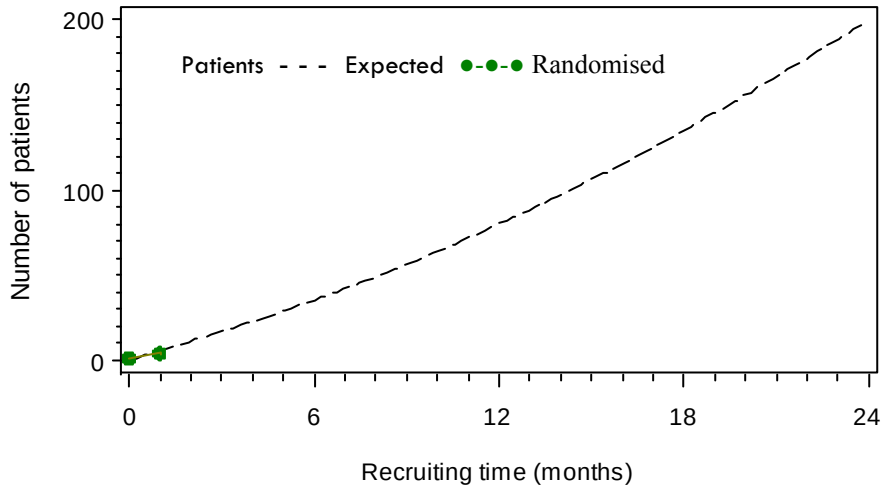
Recruitment

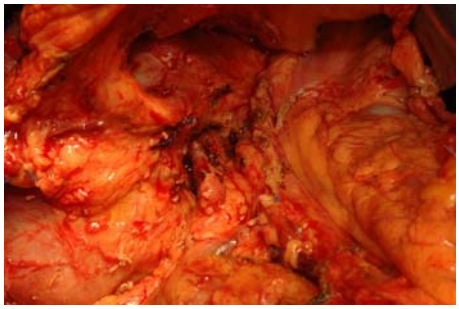
The graphic below shows the status quo and the aimed setpoint of randomized patients. After initiation of Mannheim on September,1st and also Freiburg in a short time, we hope recruitment will make good progress.



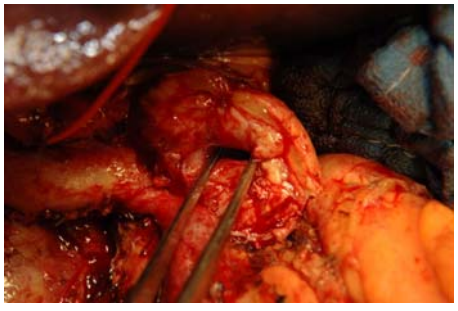
Looking Forward

To date, **4 patients** have been recruited and the first patient underwent surgery according to Whipple. Below you can view some photos of the first surgery :

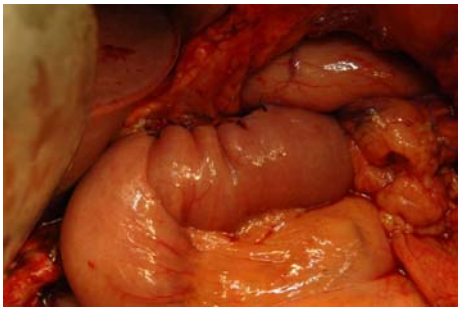
Pancreatic head after opening of the lesser sack



Pancreatic tail after resection of the head (large pancreatic duct)



Pancreaticojejunostomy



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If there are any questions or you need any assistance feel free to contact us:

Dr. Claudia Bauer
Tel: 06221-56-6984
claudiam.bauer@med.uni-heidelberg.de

With kind regards from Heidelberg

The ChroPac Team at the SDGC

Christoph M. Seiler

Claudia Bauer

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