






Newsletter 3 – 02/2010

Topics

-  Editorial
-  Recruitment and suspicion of malignancy
-  Screening lists
-  Documentation
-  Looking forward



Editorial

Dear Members of the ChroPac Study Group

According to the most recent data of the German Institute for the Hospital Remuneration System in 2008 only 399 duodenum preserving pancreatic head resections (DPPHR) were performed. Taken into account that alcohol is the major cause for chronic pancreatitis and alcoholism is a frequent disease in Germany this is a rather low number for an effective treatment.

ChroPac aims to prove whether there is a better Quality of Life for patients that are treated with a DPPHR method compared to the Whipple procedure. A substantial increase of procedure may be a consequence, if ChroPac does show such an improvement.

The focus of ChroPac is on patients with a typical clinical history suspicious for chronic pancreatitis in the pancreatic head. If patients have a pancreatic head enlargement demonstrated by imaging methods a malignancy can only be ruled out by histology. Please include and randomize such patients and accept a remaining uncertainty. If during surgery a carcinoma is shown the patient has to be treated according to the standards (e.g. pylorus preserving or classical Whipple). We have to accept, as in prior trials in the same patient population, that some chronic pancreatitis patients in fact have a carcinoma and this has also happened already in the ChroPac Trial.

Most of the participating centers are know ready to start and include patients. We have to increase our efforts to include more patients and therefore you may think about information about the trial in your local networks with gastroenterologists or in the local newspapers. We would be happy to assist you with appropriate materials such as slides or a press release.

Within this year we have to randomize at least 100 patients and therefore all your support is needed.

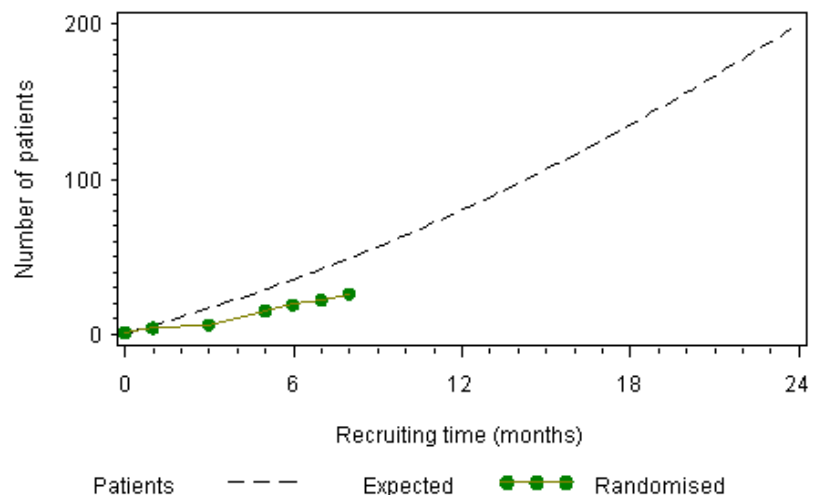
With best regards,
Christoph M. Seiler, MD



Recruitment and suspicion of malignancy

Most of the centers are now initiated. We welcome the centers Munich LMU, Munich TU and Leipzig that have been initiated since the last newsletter.

The recruitment is still too slow and we are far behind our schedule. One reason may be that centers do only screen patients if there is no suspicion of malignancy at all. However, only patients with a high-grade suspicion of malignancy (i.e. with high level of tumour markers) should not be screened. All other patients should be screened and included, as a malignancy can only be excluded during the operation (frozen section). If during or after the operation a malignancy is confirmed, the patients remain in the trial and are fully documented (ITT-intention-to-treat principle). Naturally, the surgeon has to change the operation technique in these cases according to existing guidelines.



updated: 15/02/2010

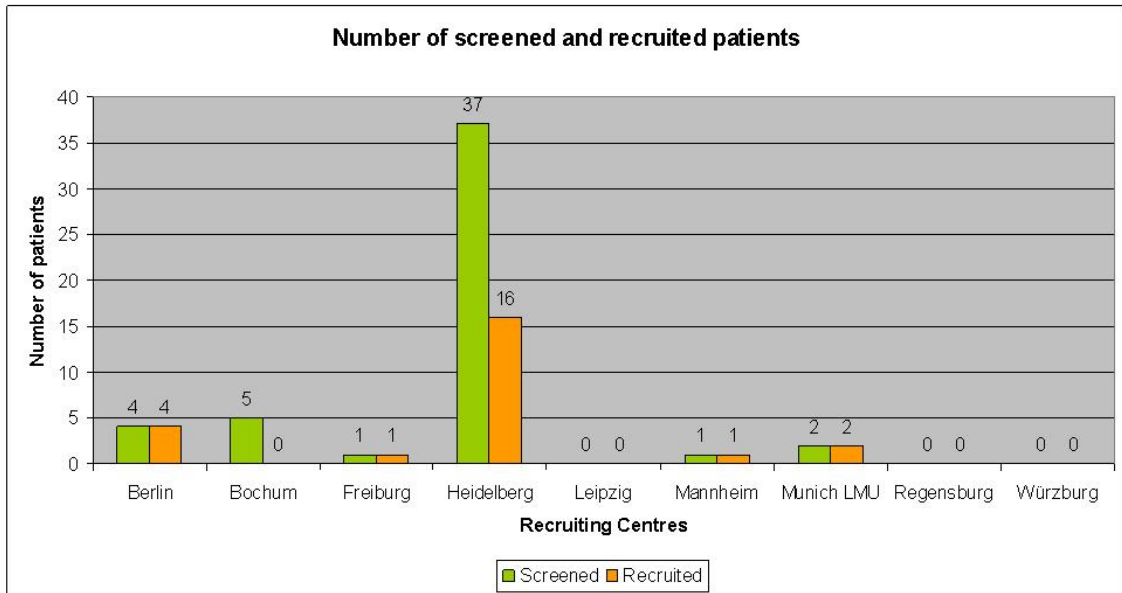
We are confident that also the other initiated centers will now recruit patients. In case any problems occur, please, do not hesitate to let us know.



Screening lists

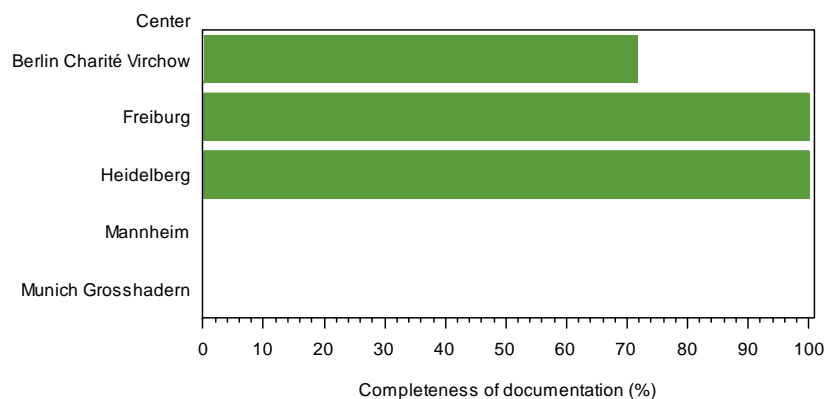
The initiated centers received in January a letter asking you to send copies of your screening list to the coordination office. The reason for this procedure is that the trial is funded by the Deutsche Forschungsgemeinschaft. Funds will be released in tranches after having recruited determined patient numbers. If patients can not be included due to several reasons (criteria not fulfilled, patient refuses to participate in the trial etc.) we are at least able to prove with the screening lists that the centers are working. Below you find

a graph showing the data of the screening lists we received by January 31st. We are looking forward to the see first patients randomized in Bochum, Leipzig, Regensburg and Würzburg.



Documentation

Overall documentation is quite good with an average of 84 % (please refer to the graph below), some centers demonstrating excellent records with close to 100 %. We will keep you informed on this issue regularly.



We kindly ask you to document the data within a timeline of 2 to 4 weeks, in order to keep the data base up to date.



Looking Forward

We want to introduce our colleague Dr. Alexandra Moreno Borchart. She has been working as a trial coordinator at the SDGC since 2007. Until further notice she will be substituting Dr. Claudia Bauer. If any questions arise, please do not hesitate to contact her:

alexandra.morenoborchart@med.uni-heidelberg.de

If there are any questions or you need any assistance please feel free to contact our team.

Dr. Alexandra Moreno Borchart
Tel: 06221-56-37728
alexandra.morenoborchart@med.uni-heidelberg.de

Elena Buss
Tel: 06221-56-6540
elena1.buss@med.uni-heidelberg.de

With kind regards from Heidelberg

The ChroPac Team at the SDGC



Christoph M. Seiler



Alexandra Moreno Borchart



Elena Buss

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