






## **Newsletter 2 - November/ 2009**

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### Editorial

Dear members of the ChroPac-study group,

With our second newsletter we would like to inform you about the progress of the ChroPac-trial nearly 6 months after it has started.

After initial delay the amount of recruited patients has augmented in the last two weeks. This reflects the efforts of the centers Heidelberg and Berlin. We hope that the other, already initiated centers will also increase the number of participating patients very soon. You will find more details in the paragraph "Recruitment" below.

We are glad to inform you, that one new center, Hospital of Augustinerinnen in Cologne, has joined the ChroPac-trial.

With the beginning of the study a few discrepancies between the study protocol and the CRF and also inside the study protocol occurred (e.g. "Bassi" - definition for pancreatic fistula). So we have written an amendment to the study protocol, which you will receive within a short time.

With best regards,

Christoph M. Seiler, MD

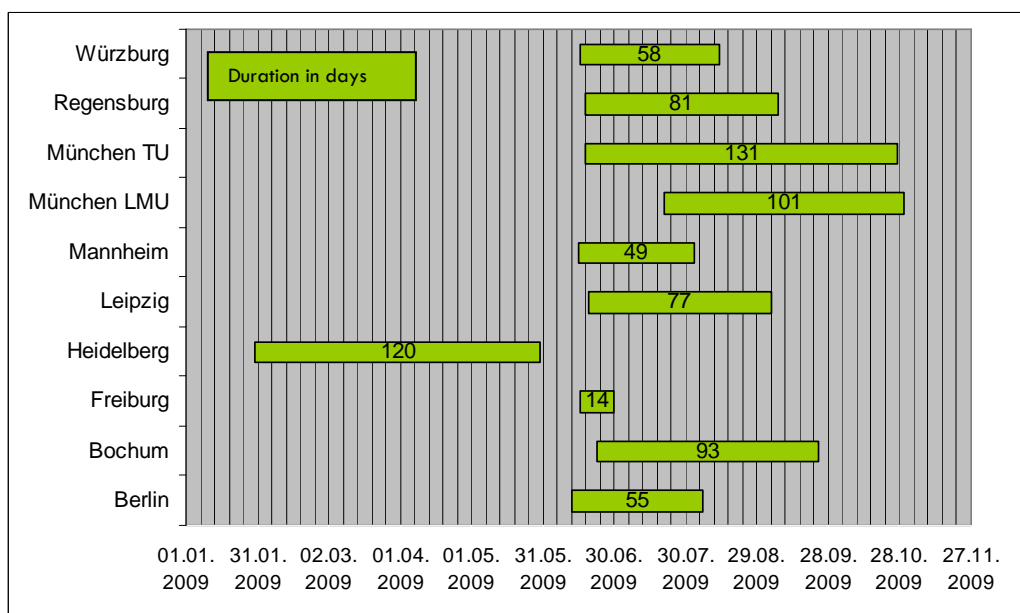


### Current state of participating centers

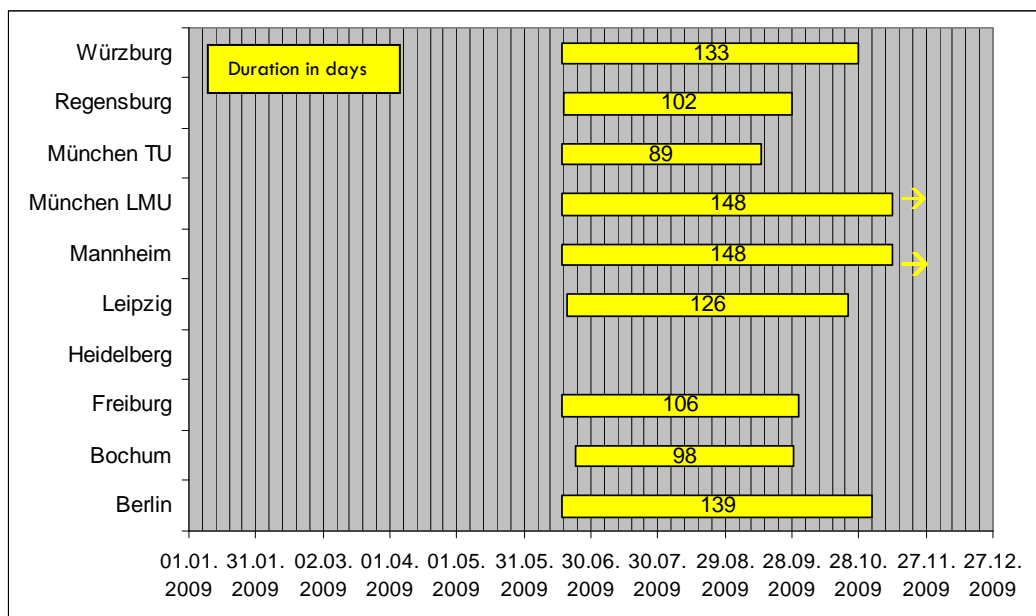
The progress of the ChroPac trial was in the beginning quite slowly but fortunately it seems to change in the last days. One reason for delayed start surely was that start time was in summer time, which made it difficult to contact all persons involved in the study.

Furthermore, long lasting ethics approval procedures and delays in return of duly signed contracts postponed the initiation of the participating centers. But now we hope that together we can move the trial forward.

1. Status quo of ethics approval procedures: As you can see in the graphic below duration of ethics procedures varied greatly at the individual centers. This was due to the different processing of applications and to varying requirements made by the ethics committees. Three committees (Berlin, Regensburg, Freiburg) assented unconditionally to the first approval of Heidelberg. The others required mainly minor formal modifications in the patient information form. The following two requirements were made frequently: first, we had to point out that no particular patient insurance is contracted and second, the item “Pseudonymisierung” should be better explained.



2. Status quo of contract procedures: In some trial centers it seems to take a long time to get the contract approved by the legal adviser and to get it signed by the hospital administration. Since the administration of some centers wished to sign the contract last, it had to be sent repeatedly back and forth taking lot of time.

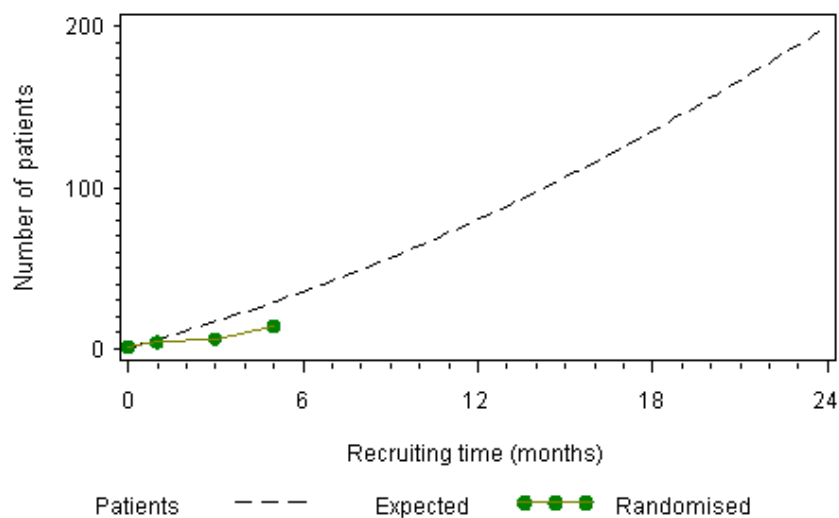


In total, 7 centers are initiated at present (Berlin, Bochum, Freiburg, Heidelberg, Mannheim, Regensburg, Würzburg) and 3 centers (München LMU, München TU and Leipzig) will be initiated this very month.



## Recruitment

Initially, recruitment was slow. But now 14 patients have been randomized and they were screened in Heidelberg and Berlin. 8 patients have been recruited within the last 2 weeks.



First patient in: 10.06.09

updated: 10.11.09

We are confident that also the other initiated centers will now recruit patients. In case any problems occur, please, let us know.



## Initiation

Our monitor for the ChroPac-trial, Daniela Jackson, reported that all initiation dates ran smoothly and we thank all centers for their good prearrangements. Many open questions were answered during initiation. One problem was raised which we want to mention notably. Some centers told us about difficulties to maintain blinding due to lack of staff or staff change. We understand these problems, but we want to point out that **conditions of blinding have to be kept** since otherwise serious bias problems may occur and the outcome of the study is at risk.



## Looking forward

We want to introduce our new colleague Elena Buss to you. She is a nurse and bachelor of nursing sciences. She has gained some experiences in clinical trials at the Charité, Berlin. Now she will be in charge of the ChroPac–study as a trial assistant at the SDGC.

We hope all centers will be initiated till the end of the year and recruitment of patients will make a huge progress so far.

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

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With kind regards from Heidelberg

The ChroPac Team at the SDGC



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