

## Newsletter 10 – 08/2013

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### Editorial

Dear Members of the ChroPac Study Group,

We are very proud to inform you that recruitment is almost completed now and that only **7 more patients** have to be included. Thus, the randomization goal is not only in sight but even within the reach.

On our way we had to deal with challenges such as declining numbers of eligible patients and the need to increase the sample size. This postponed our schedule, but with our collective effort we have mastered these challenges.

With 7 more patients needed, you still have the chance to randomize patients. As already communicated via email, with your support we feel confident to reach this milestone by the end of October.

Thank you all very much for your effort throughout the trial as well as for this final spurt.

With best regards,

Markus Diener, MD



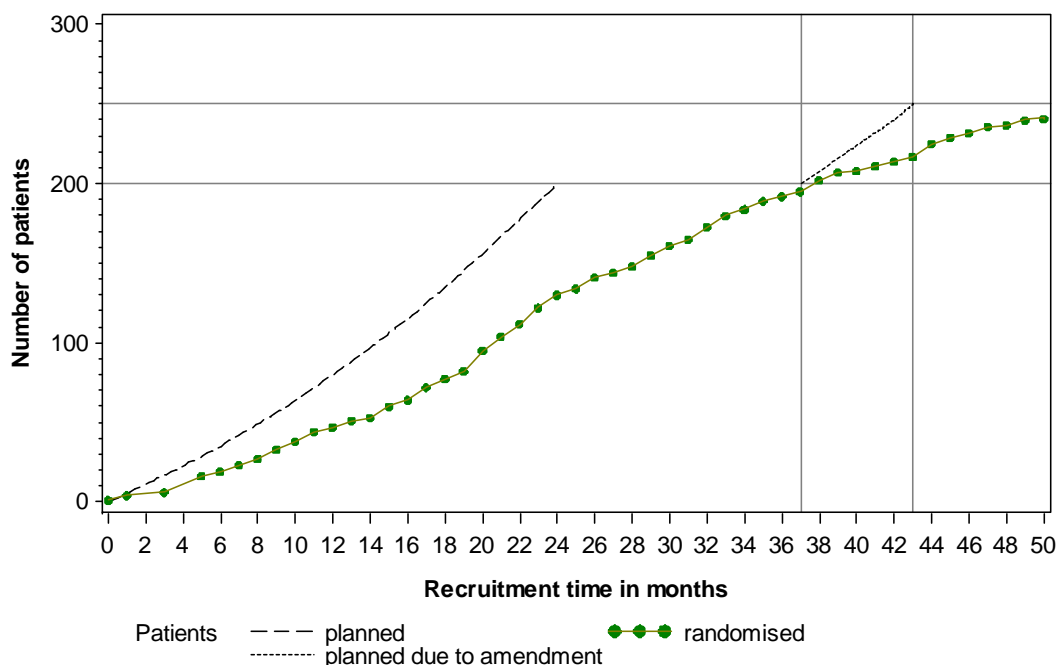
## Visits

Please make every effort to obtain data for the primary endpoint i. e. QLQ. If a patient refuses a clinical visit, this should be performed as telephone visit in order not to miss any data. Additionally, each center should suggest the possibility of sending the questionnaires by post. This has to be documented in the ISF.



## Recruitment

Currently, 243 subjects have been randomized (for development of recruitment see figure 1 below).



First patient in: 10/06/2009

(updated 06/08/2013)

Figure 1.



## Screening & Randomization

Screening and randomization numbers (72 screened vs. 24 randomized subjects) during the first half of this year show that one third of all screened patients have been randomized. The most frequent reasons for not randomizing were suspicion of cancer and refusal of informed consent. Screening and randomization numbers per center are given in figure 2.

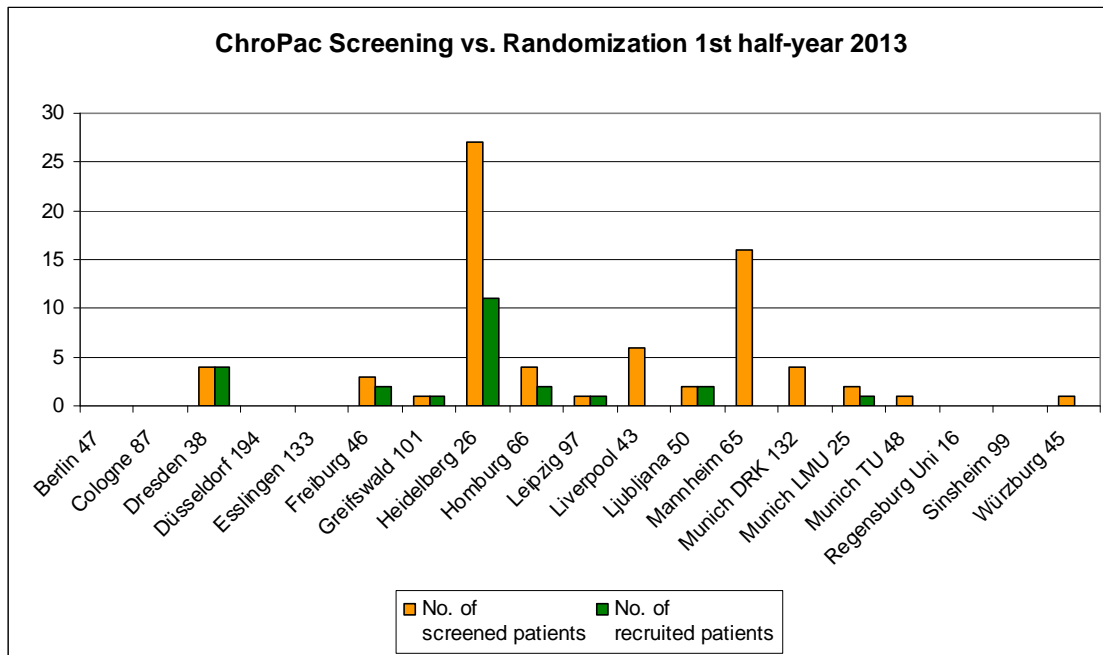
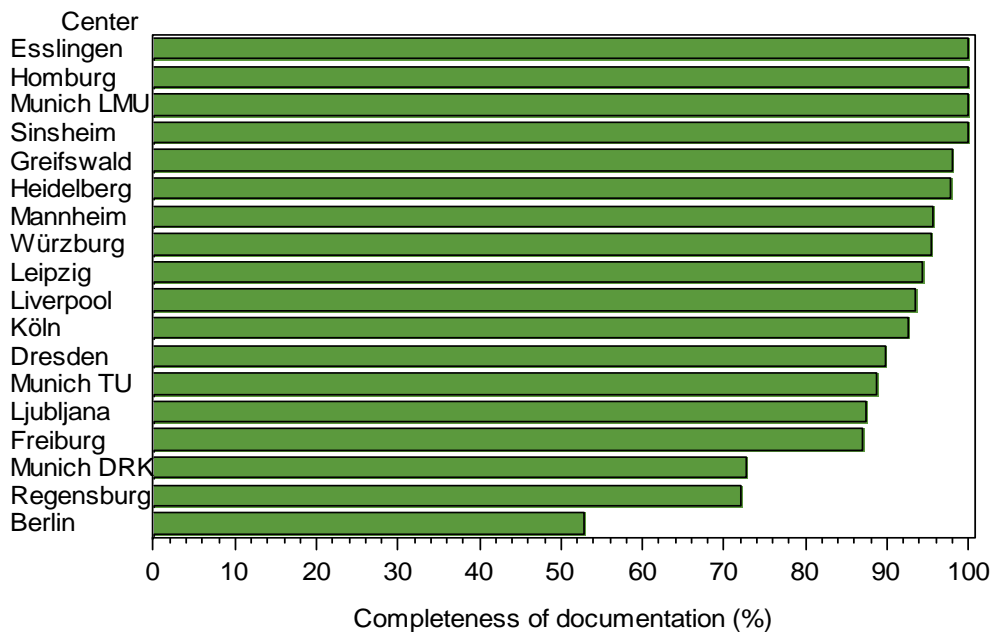


Figure 2 on basis of screening data that were provided by centers



## Documentation Status

In July, the average documentation status for all centers was almost 93%. Thanks to all centers for this effort. Currently, four centers have even reached 100% completeness of documentation.





## Looking Forward

As soon as recruitment is completed and the trial is changing into its follow-up phase we need to concentrate on collecting excellent follow-up data in order to ensure ChroPac trial's high quality.

For questions or comments feel free to contact us.

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With kind regards from Heidelberg  
The ChroPac Team at the SDGC

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