









Newsletter 6 – 07/2011

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Editorial

Dear Members of the ChroPac Study Group,

We are very happy to see that patient enrolment for ChroPac trial is well on the way now. Our target of 200 patients is already in sight and we hope to be able to finish randomisation in the first quarter of 2012.

As in 2009/2010 recruitment was far behind schedule we decided to enlarge the number of participating centers. Thanks to the increased engagement of many of the “old” centers and the motivation of the “new” centers, that were initiated in the end of 2010 and the beginning of 2011, the recruiting rate was stimulated: in 2010 we had a recruiting rate of 1,2 patients per week, in the first half of 2011 we recruited 2,1 patients per week. Please continue to increase your efforts to help the trial to achieve its goal!

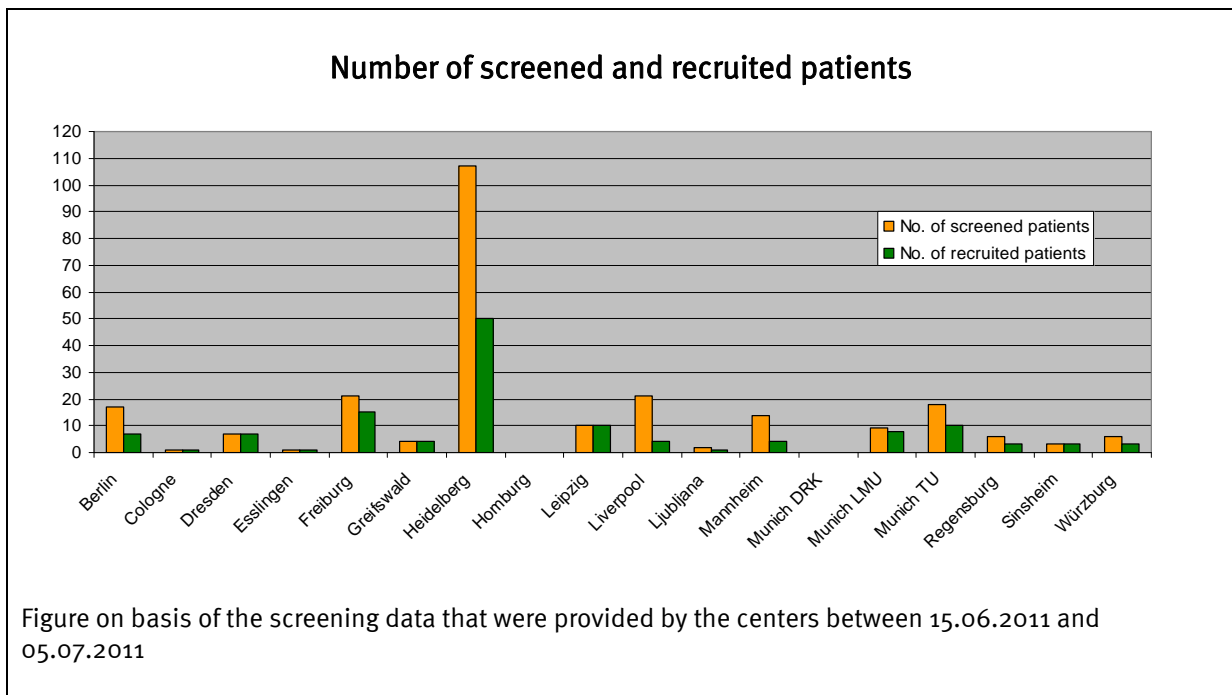
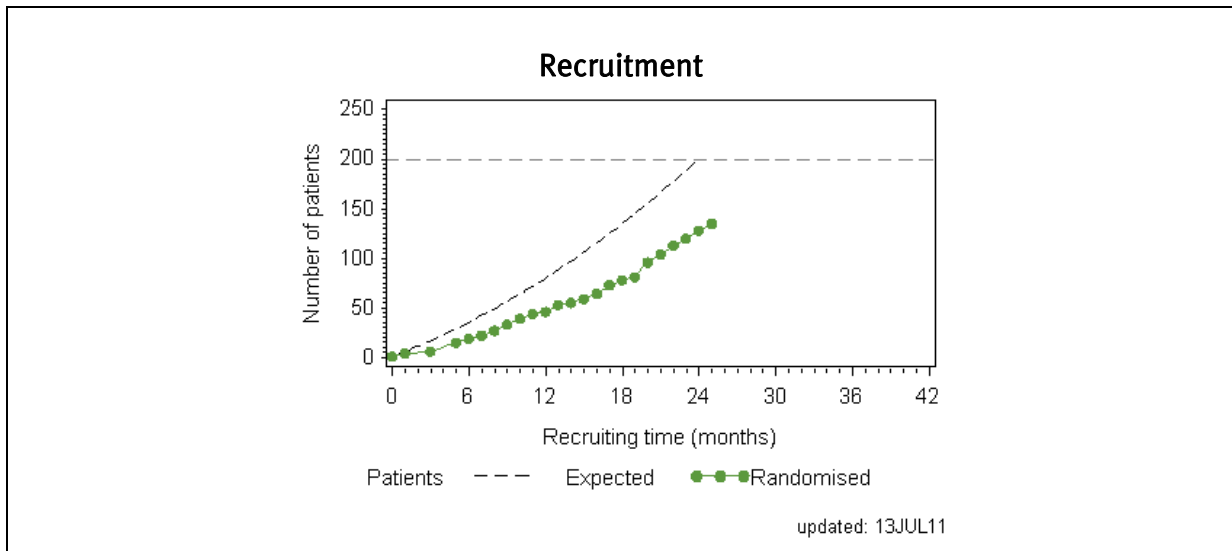
With best regards,
Markus Diener, MD



Recruitment

We welcome the centers Esslingen (Klinikum Esslingen, Prof. Dr. L Staib), Homburg (Prof. Dr. Schilling, Dr. Moussavian), Greifswald (Universitätsmedizin Greifswald, Prof. Dr. Heidecke, Dr. Partecke), Munich DRK (Rotkreuzklinikum München, Prof. Dr. Schoenberg, Dr. Treitschke) and Sinsheim (Prof. Dr. Büchler, Dr. Simon, Dr. Löffler) that have been initiated. The initiation process is now completed and there are a total of 18 centers recruiting for the trial.

For recruiting numbers please refer to the following two figures:



Randomizer & Screening numbers

As there has been some confusion about the randomizer number, screening number and patient number generating time consuming queries, we would like to remind all participants:

- screening number: 3-digit, beginning with 001
- the screening number has to be used as patient number (patient ID) in QLQ-forms and for documentation in MACRO
- the randomization number is assigned electronically by www.randomizer.at



Primary Endpoint & QoL-Questionnaires

The primary endpoint is the average **Quality of Life** during 24 months after surgery, measured 6, 12 and 24 months after surgery by the EORTC QLQ-C30 and PAN 26 questionnaires. Unfortunately, centers and/or patients have lost some of the questionnaires. The table below gives an overview of the number of **missing questionnaires**:

Center	Visit 1 Screening		Visit 4 6 months after operation	
	missing	due	missing	due
Berlin	2	6	2	5
Cologne	0	0	0	0
Dresden	0	6	1	2
Esslingen	1	1	0	0
Freiburg	1	13	3	9
Greifswald	0	4	0	0
Heidelberg	5	50	10	36
Leipzig	1	10	1	5
Liverpool	1	4	2	2
Ljubljana	1	1	0	0
Mannheim	1	4	1	3
Munich DRK	2	2	0	0
Munich LMU	2	7	3	5
Munich TU	1	11	1	6
Regensburg	3	3	1	1
Sinsheim	0	3	0	1
Würzburg	0	3	0	2
Total:	21	128	25	77

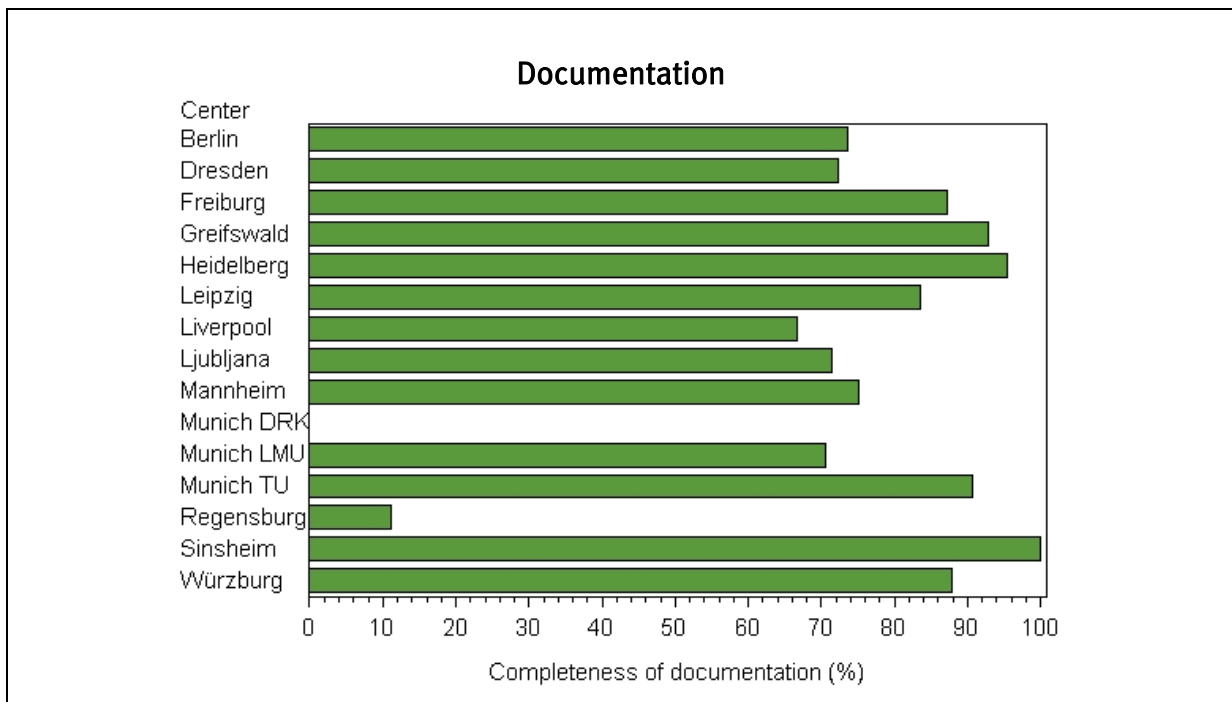
Updated July 4th 2011

At the moment 21 from 128 questionnaires (16,4 %) concerning visit 1 are missing. **Please make sure to get back all questionnaires from the patients and send them immediately to the data management!** The questionnaires are indispensable for the evaluation of the primary endpoint and thus for reaching the goal of our trial.



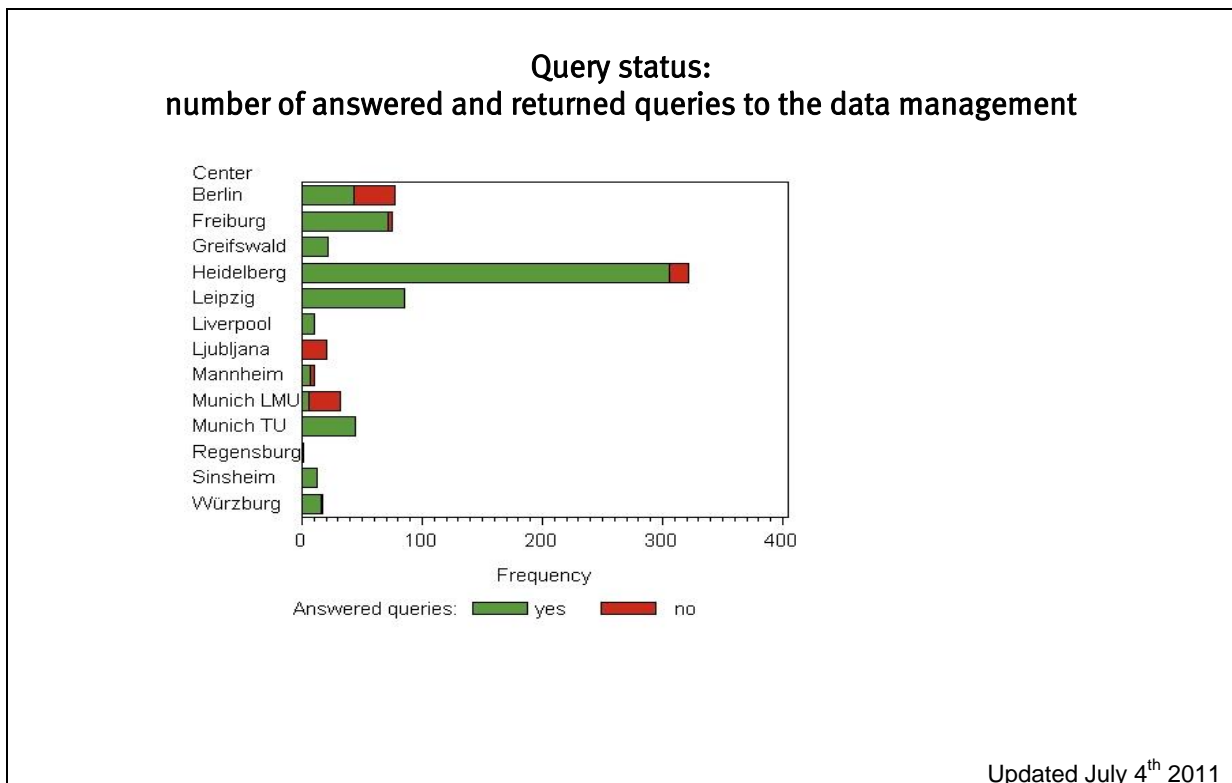
Documentation

Overall documentation is improvable with an average of 84,8 % as of July 4th 2011. For detailed information please refer to the graph below.



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

Some of the centers have already received queries (see below). We kindly ask you to answer the queries as soon as possible.





Milestones

Due to low recruitment the milestones have been adapted in May 2010 (see below), assuming a recruiting rate of 2 patients per week. 80 patients have been recruited in one year between June 1st 2010 and May 31st 2011. This makes a recruiting rate of 1,5 patients per week.

We would like to encourage you to put all your efforts in recruiting, since we are approaching our goal of 200 patients and hope to reach it in the first quarter of 2012.

Original schedule (grant application)			Adapted schedule (May 2010)		
Milestones	Quarter	Year	Milestones	Quarter	Year
First patient in	II	2009	First patient in	II	2009
Last patient in	I	2011	Last patient in	I	2012
Patient follow-up	I	2013	Patient follow-up	I	2014
Data base closure	II	2013	Data base closure	II	2014
Data analysis	III	2013	Data analysis	III	2014
Biostatistical report	IV	2013	Biostatistical report	IV	2014
Publication	IV	2013	Publication	IV	2014



ChroPac Website

On the investigator meeting in November 2010 it was decided that the trial coordination will provide centers with information material. The material has been put at disposition on the ChroPac website: www.chropac-trial.eu



Looking Forward

We hope that you will continue to screen and randomize regularly patients in order to reach our goal of 200 patients in the first quarter of 2012. For any questions or comments please feel free to contact our project management at SDGC:

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With kind regards from Heidelberg
The ChroPac Team at the SDGC

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