







Newsletter 7 – 02/2012

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Editorial

Dear Members of the ChroPac Study Group,

We hope you have all had a good start into the New Year. During the last five months randomization has declined a bit with a rate of 1.1 patients randomized per week during the last quarter of 2011. Thus, we would like to encourage you to enrol the patients needed for completion of recruitment. Assuming that each site will randomize two more patients in the first half of this year, the sample size of 200 patients will be achieved in the second quarter of 2012. We appreciate the efforts all centers have made and we are convinced that all members of the study group will give their best to make our goal come true.

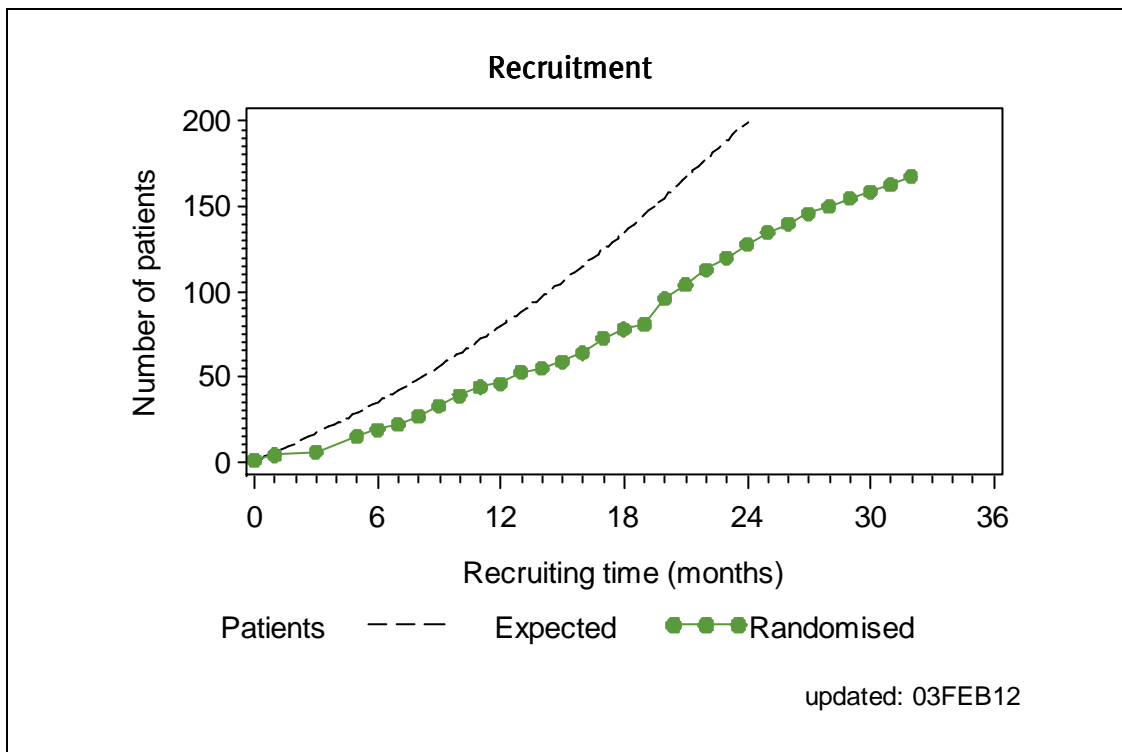
With best regards,
Markus Diener, MD



Recruitment

We welcome the center Düsseldorf (Evangelisches Krankenhaus Düsseldorf, Prof. Dr. Krämling) as our 19th group member. As soon as the ethics procedure is completed, Düsseldorf will be initiated. We do need 28 more patients to be randomized until our preset sample size is reached.

For recruiting numbers please refer to the following figure:



Screening & Randomization Numbers

As shown in the figure below, 96 patients were screened for eligibility in the first half of 2011, whereas in the second half only 68 subjects were screened. Please go on in making all reasonable efforts to enrol each eligible patient.

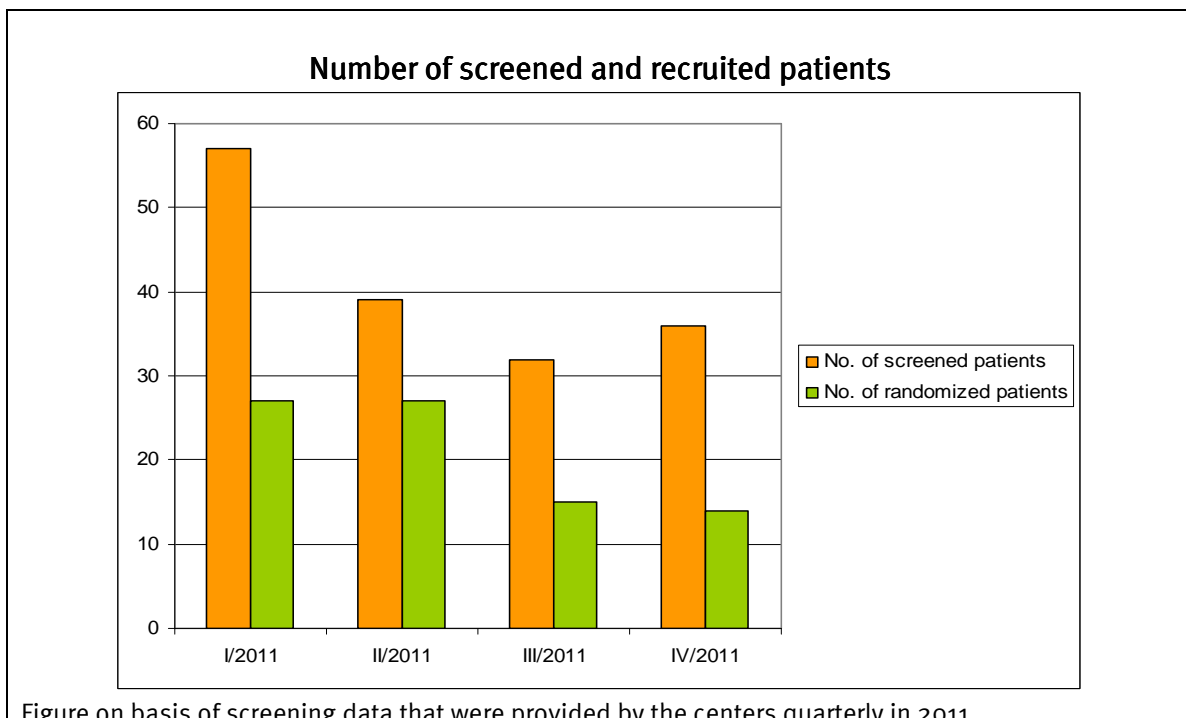


Figure on basis of screening data that were provided by the centers quarterly in 2011

	Quarter I	Quarter II	Quarter III	Quarter IV
Subjects screened: s	57	39	32	36
Subjects enrolled: e	27	27	15	14
Percentage e/s	47	69	47	39

Table on basis of screening data showing that also the percentage of enrolled patients to screened patients was decreasing in the last two quarters



Primary Endpoint & QoL-Questionnaires

Primary endpoint for ChroPac trial is the average **Quality of Life** during 24 months after surgery, measured 6, 12 and 24 months after surgery by EORTC QLQ-C30 and PAN 26 questionnaires. Therefore, QoL questionnaires are the most crucial data needed to answer the trial question. The table below gives an overview of the rate of available questionnaires compared to due questionnaires (updated on 16/01/2012):

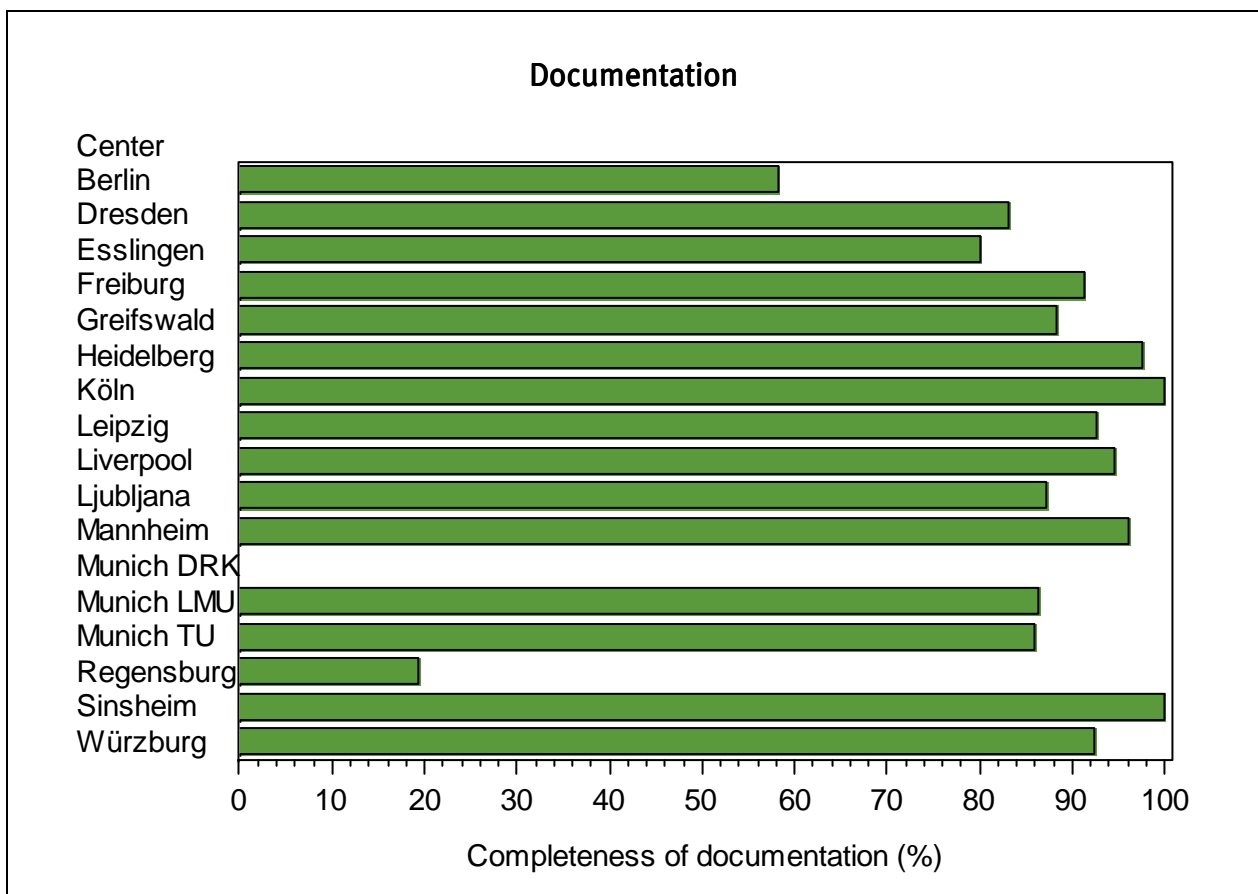
Center	Visit 1	Visit 4	Visit 5	Visit 6
Berlin	4/6	3/6	3/5	0/3
Dresden	8/8	5/7	0/2	0/0
Esslingen	1/1	0/1	0/0	0/0
Freiburg	13/15	8/14	7/11	1/4
Greifswald	6/6	4/4	0/0	0/0
Heidelberg	50/55	39/50	30/37	12/20
Köln	3/3	1/1	0/0	0/0
Leipzig	12/12	7/10	4/5	0/1
Liverpool	5/5	3/4	1/2	0/0
Ljubljana	2/4	1/1	0/0	0/0
Mannheim	6/6	3/5	3/5	1/3
Munich DRK	0/2	0/2	0/0	0/0
Munich LMU	10/11	4/8	3/6	0/3
Munich TU	16/17	7/11	2/6	0/0
Regensburg	1/3	0/3	0/1	0/0
Sinsheim	4/5	3/3	2/2	0/0
Würzburg	3/3	3/3	2/3	0/0
Sum	144/162	91/133	57/85	14/34
percentage	88.9	68.4	67.1	41.2

At present, 18 from 162 questionnaires (11.1 %) concerning visit 1 are still missing. Please make sure to get back all questionnaires from your patients and to send them immediately to the data management.

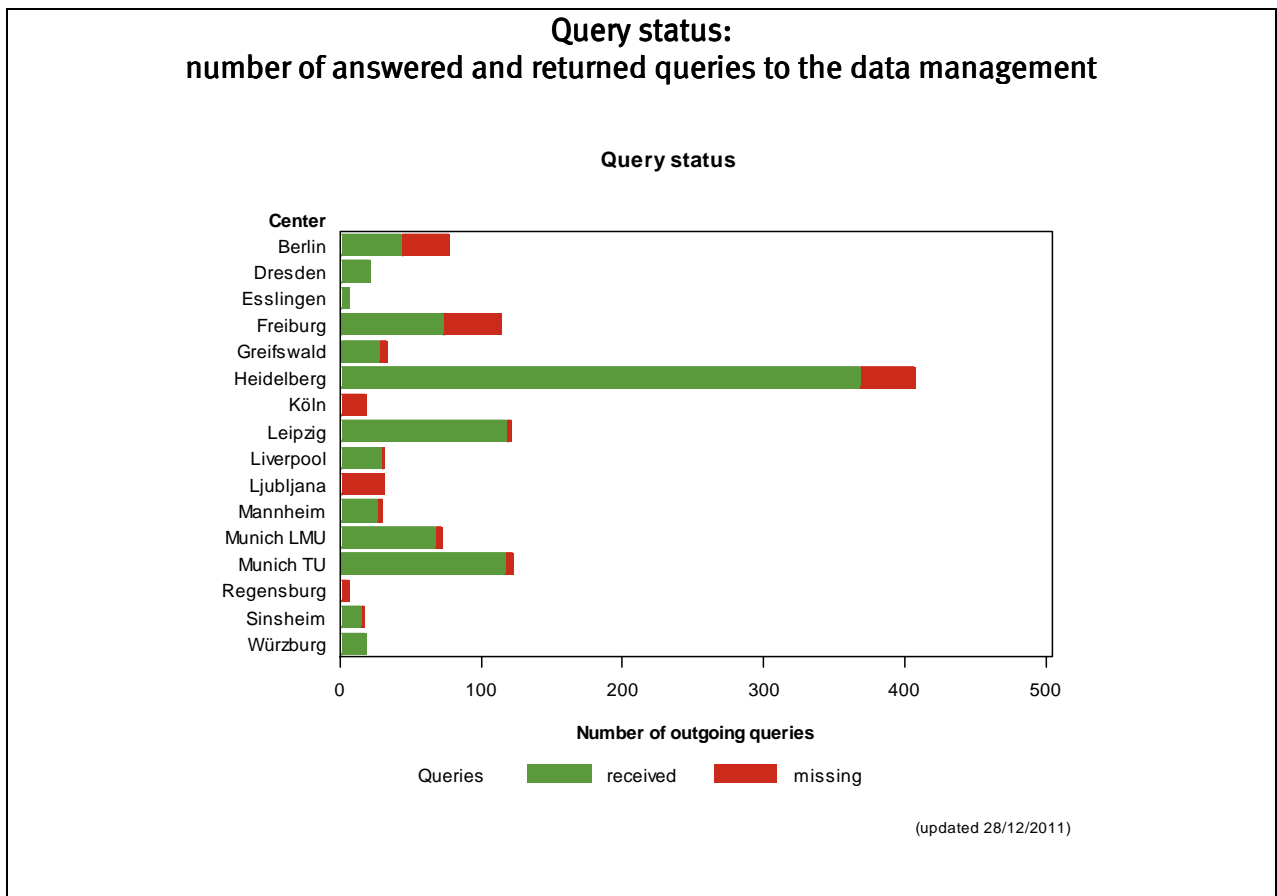


Documentation

Completeness of documentation as of February 3rd 2012 (The average of all centers is currently 89%). For detailed information please refer to the graph below.



We kindly ask you to document the data within 4 weeks and answer the queries as soon as possible, in order to keep the data base up to date. Query status is given in the following graph.



Looking Forward

The goal of our trial is now just in sight and we feel confident to reach it in the first half of 2012. Please let us make a final spurt to enrol the last 28 patients needed.

For question or comment please contact our project management:

Colette Dörr-Harim

(colette.doerr-harim@med.uni-heidelberg.de, Tel 0049-(0)6221-5636683) or

Evelin Hund

(Evelin.hund@med.uni-heidelberg.de, Tel 0049-(0)6221-566540)

or visit our homepage:

www.chropac-trial.de

With kind regards from Heidelberg

The ChroPac Team at the SDGC

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