







## Newsletter 4 – 05/2010

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### Editorial

Dear Members of the ChroPac Study Group,

After obtaining ethical approval for our ChroPac trial and international registration our trial protocol has now been published in the open access journal *Trials* (IF 1,74). The next important steps are recruiting the calculated sample size of 200 patients and completing the two years follow up for each patient. As this is one of the few surgical trials with Quality of Life as primary endpoint it is essential to obtain the relevant questionnaires from the patients.

We are still behind our scheduled recruitment curve and therefore I encourage all to inform your partners in gastroenterology about ChroPac. Patients with chronic pancreatitis do exist and surgery is an effective treatment. The patient organization “Arbeitskreis der Pankreatektomierten e.V.” (AdP; [www.adp-dormagen.de](http://www.adp-dormagen.de)) in Germany is supporting our trial and recommends that patients with chronic pancreatitis eligible for ChroPac should participate. We thank the AdP for their support and hope this will increase recruitment.

Please let us know if you need support at your center and we will be happy to assist you in any way.

With best regards,  
Christoph M. Seiler, MD

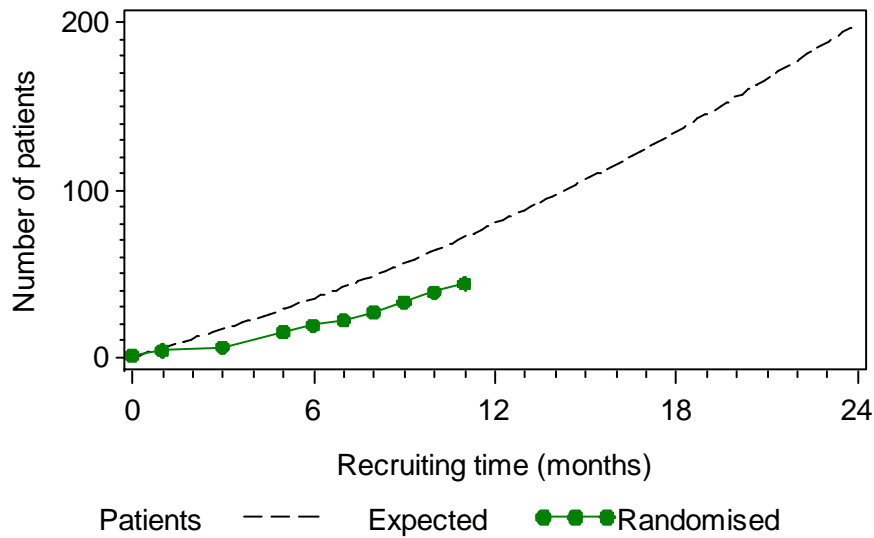


### Recruitment

We welcome Dr. Ales Tomazic and Professor Mirko Omejc from Ljubljana, their center has been initiated on March 18<sup>th</sup>.

The recruitment is still slow and we are behind our schedule. For exact numbers please refer to the following two figures.

### Recruitment



updated: 25MAY10

### Number of screened and recruited patients

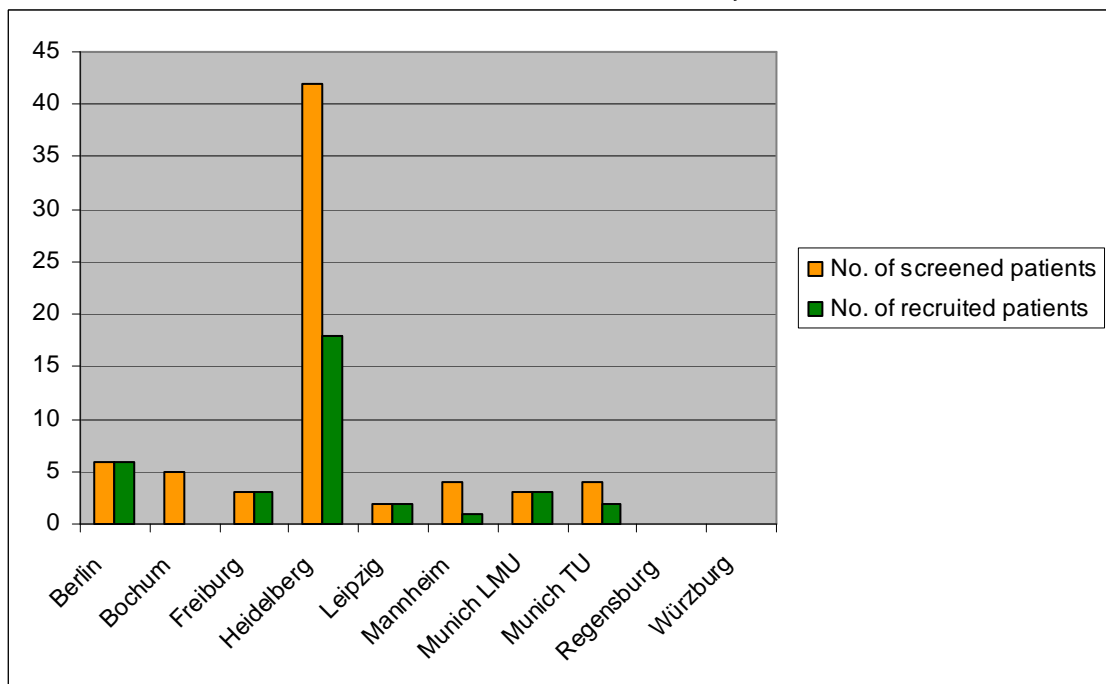
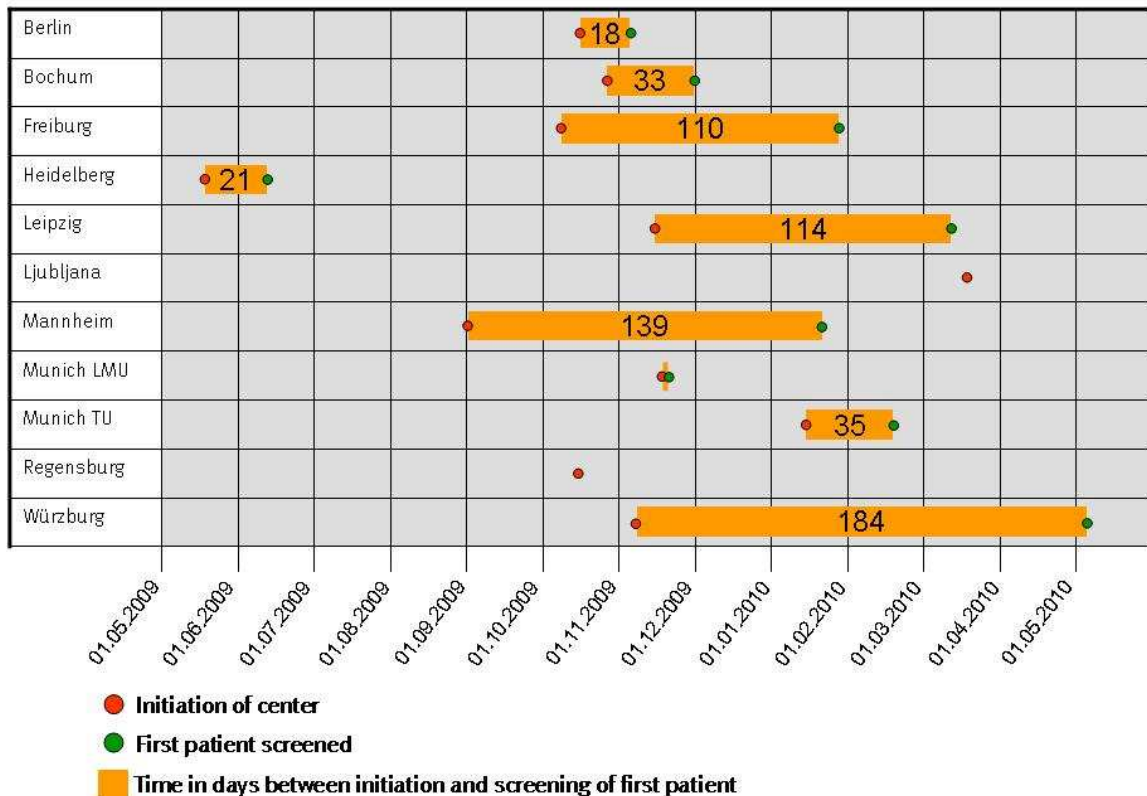


Figure on basis of the screening data that were provided by the centers by 31.03.2010. In the meantime Würzburg has recruited two patients.

The figure below shows the period of time between the initiation and the first screened patient for each center. The time span varies considerably between the centers.

Period of time between the initiation and the first screened patient



## File note no. 2

Lately, the centers received the file note no. 2 concerning the documentation of:

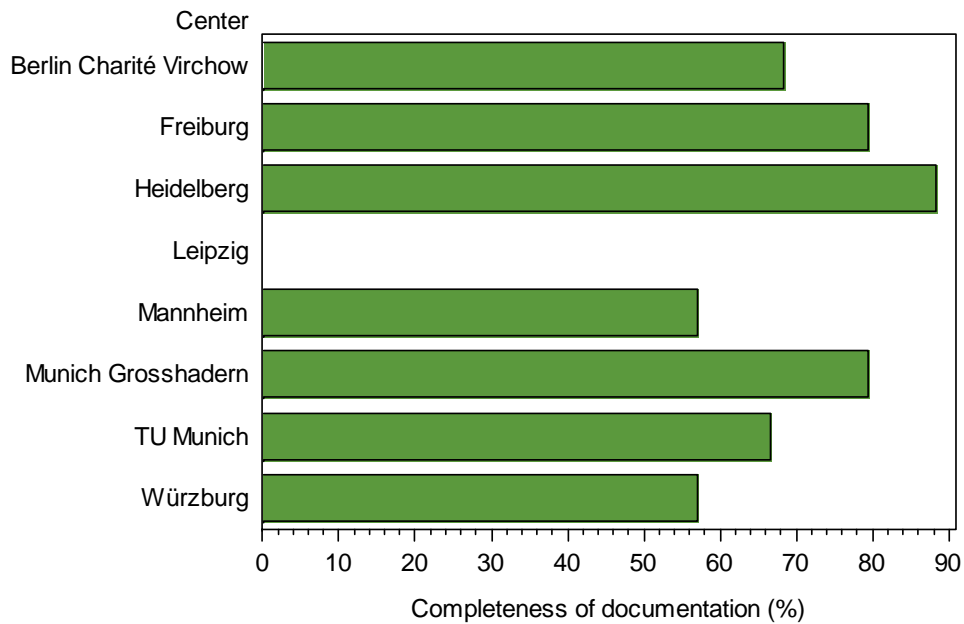
- delayed gastric emptying
- new onset of diabetes mellitus
- development of exocrine insufficiency
- re-intervention due to chronic pancreatitis

These events are appearing in the **long term** and are documented as secondary endpoints. In order to minimise workload it was decided that there is no need to complete an additional SAE report for these events. However, other acute events, that are also secondary endpoints but become relevant in **near term** need to be reported as SAEs.



## Documentation

Overall documentation is quite good with an average of 83,7 % as of 5<sup>th</sup> May 2010. 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.



## Publication


The ChroPac protocol has been published and acknowledges all participating centers:

MK Diener, T Bruckner, P Contin, C Halloran, M Glanemann, HJ Schlitt, J Mossner, M Kieser, J Werner, MW Büchler and CM Seiler

**ChroPac-Trial: Duodenum-preserving pancreatic head resection versus pancreatoduodenectomy for chronic pancreatitis. Trial protocol of a randomised controlled multicentre trial**

Trials 2010 April 29; 11:47

Diener et al. *Trials* 2010, 11:47  
<http://www.trialsjournal.com/content/11/1/47>



**STUDY PROTOCOL** **Open Access**

**ChroPac-Trial: Duodenum-preserving pancreatic head resection versus pancreatoduodenectomy for chronic pancreatitis. Trial protocol of a randomised controlled multicentre trial**

Markus K Diener<sup>1,2</sup>, Thomas Bruckner<sup>2,3</sup>, Pietro Contin<sup>1,2</sup>, Christopher Halloran<sup>4</sup>, Matthias Glanemann<sup>5</sup>, Hans Jürgen Schlitt<sup>6</sup>, Joachim Mössner<sup>7</sup>, Meinhard Kieser<sup>3</sup>, Jens Werner<sup>1</sup>, Markus W Büchler<sup>1,2</sup> and Christoph M Seiler<sup>\*1,2</sup>



## Looking Forward

As recruitment is still behind schedule we will have to adapt the milestones. Considering the actual recruiting activity of about 2 patients per week we will reach our goal of 200 patients in February 2012:

Original schedule			Adapted schedule		
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

With kind regards from Heidelberg  
The ChroPac Team at the SDGC

Christoph M. Seiler  
Alexandra Moreno Borchart  
Elena Buss

Sponsored by



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