



ChroPac

ISRCTN 38973832

**Duodenum-preserving head resection versus
pancreatico-duodenectomy for Chronic Pancreatitis of the head**

ChroPac



Objective

To investigate differences in

Quality of Life (QoL)

during 24 months after surgery
of duodenum-preserving pancreatic head
resection (DPPHR)

versus

pancreatico-duodenectomy (PD)



Inclusion and Exclusion Criteria



Inclusion criteria:

- Patients with chronic pancreatitis of the head and pain eligible for elective surgical resection
- Ability of subject to understand character and individual consequences of the clinical trial
- Written informed consent

Exclusion Criterion:

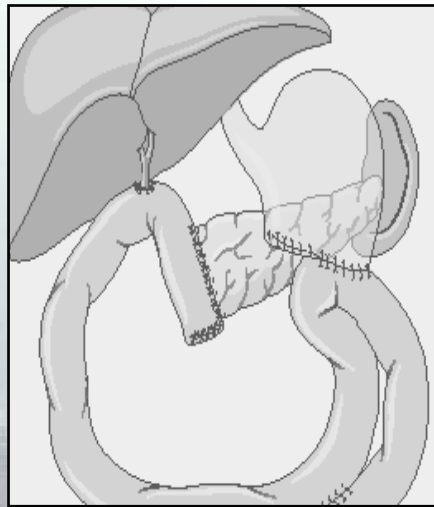
- Participation in another intervention-trial with interference of intervention and outcome of this study



Interventions

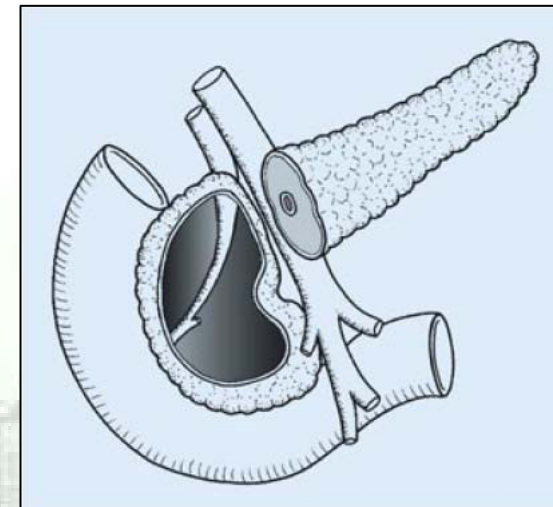
Pankreaticoduodenektomie (PD)

- Classical Whipple
- Pylorus-preserving-Whipple



Duodenum preserving Pancreatic Head resection (DPPHR)

- Beger
- Frey
- Bern





Hypothesis

- **H0: Both interventions lead to the same average QoL-score:**

$$\mu_1 = \mu_2$$

- **H1: the two interventions perform differently in terms of the primary efficacy endpoint:**

$$\mu_1 \neq \mu_2$$



Primary efficacy endpoint



**Average QoL during 24 months after surgery,
measured 6, 12 and 24 months after surgery**

**by the EORTC QLQ-C 30 scale
„Physical functioning“**

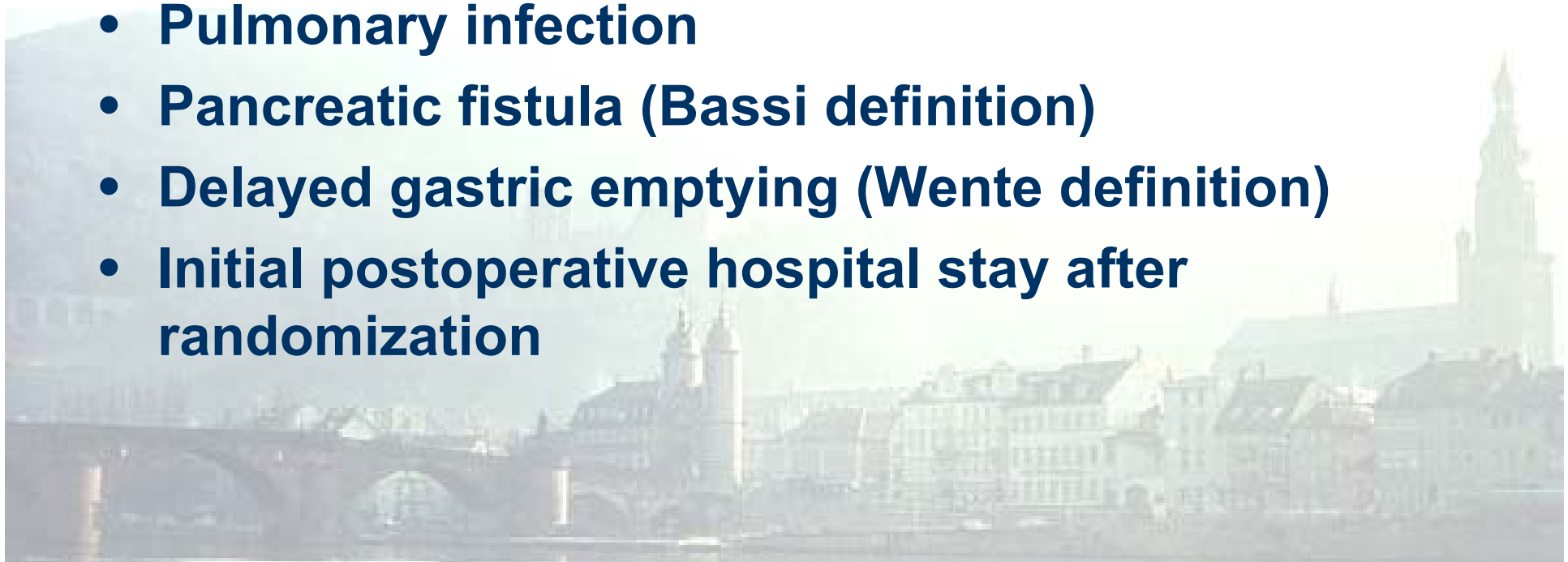




Secondary endpoints



- **Mortality, Morbidity, Wound Infection (CDC)**
- **Operation time**
- **Blood loss assessed by surgeons and anaesthesists**
- **Pulmonary infection**
- **Pancreatic fistula (Bassi definition)**
- **Delayed gastric emptying (Wente definition)**
- **Initial postoperative hospital stay after randomization**





Secondary endpoints



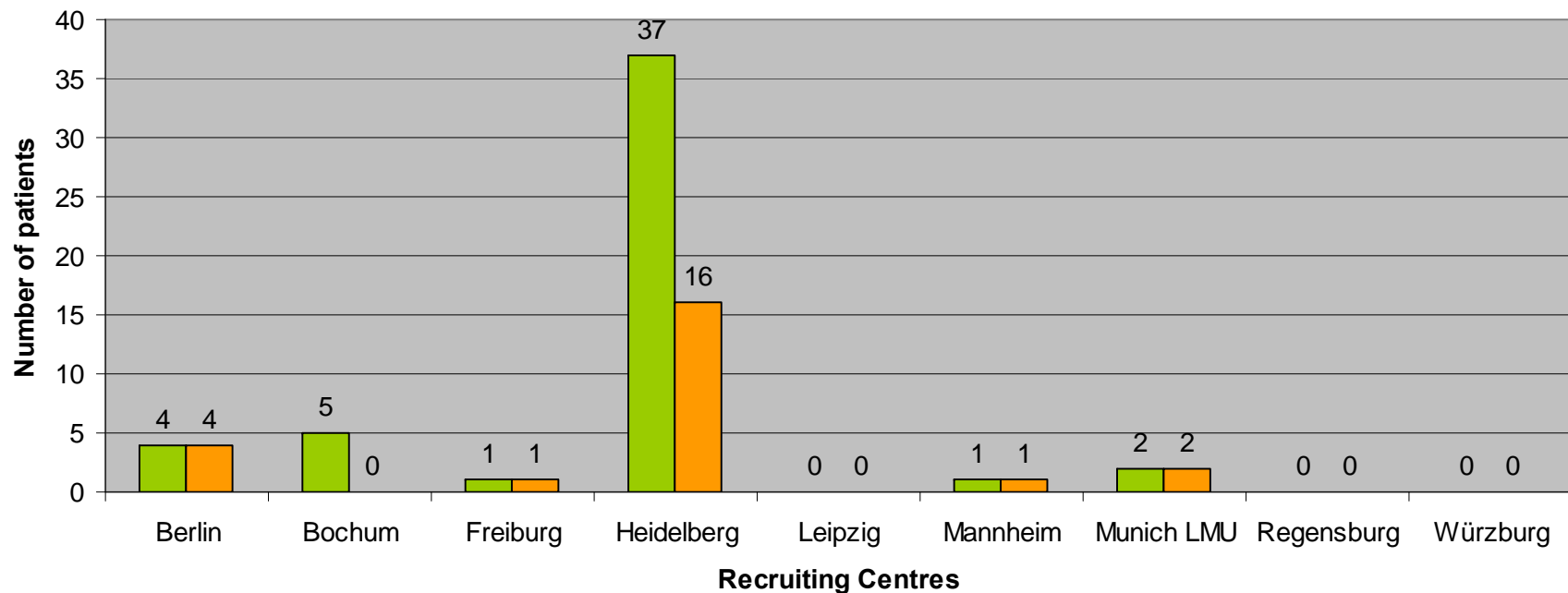
- **EORTC CLQ-C30 and PAN 26 (CP) subscores**
- **Reoperation due to recurrence of chronic pancreatitis**
- **Weight gain**
- **New onset of diabetes mellitus requiring treatment**
- **Development of exocrine insufficiency (continuous supplement of enzymes necessary)**
- **Total hospital stay after randomization**
- **Total hospital stay due to chronic pancreatitis within 24 months after randomization**



Expected Numbers

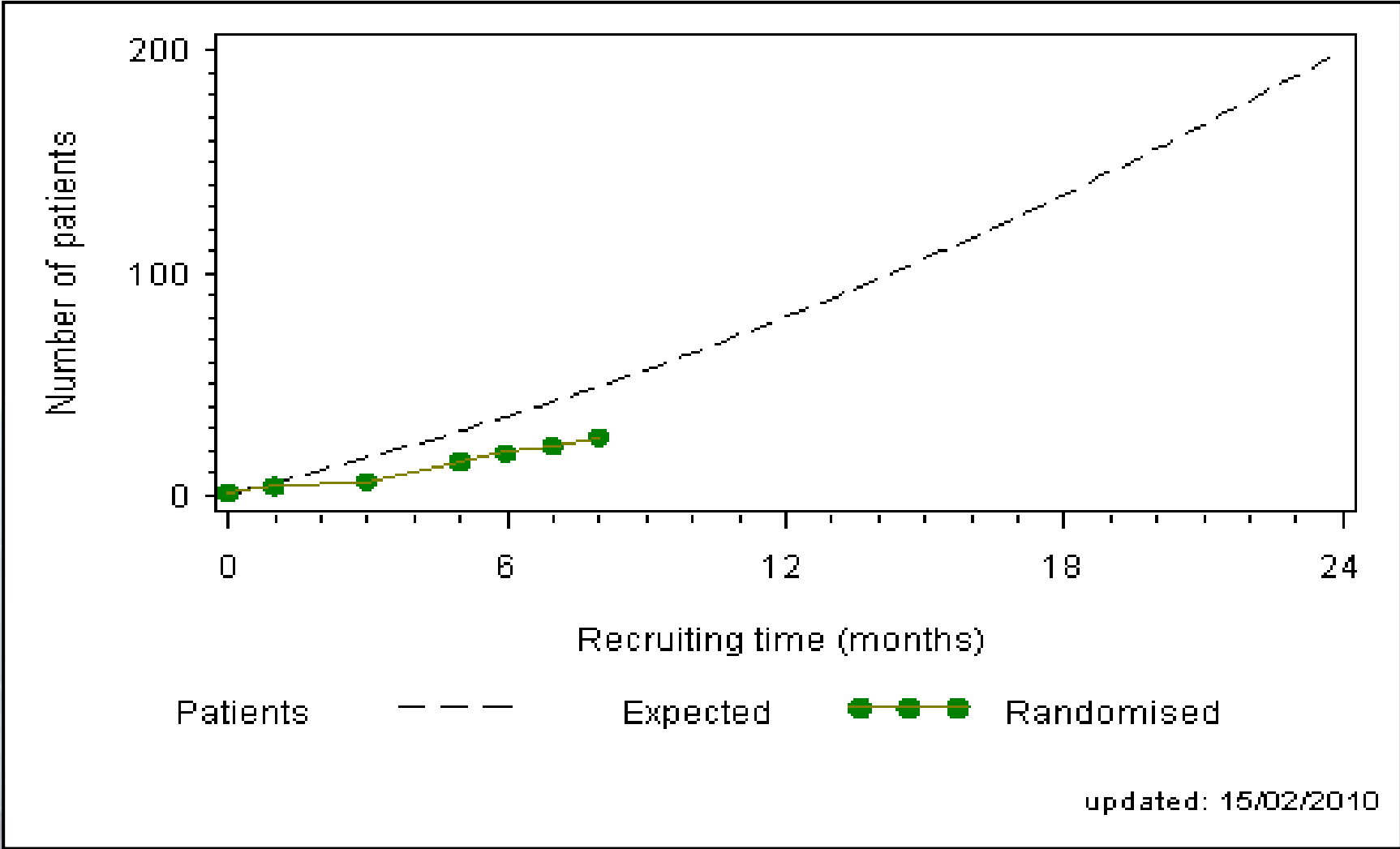


Number of screened and recruited patients





Recruitment





Participating trial centers

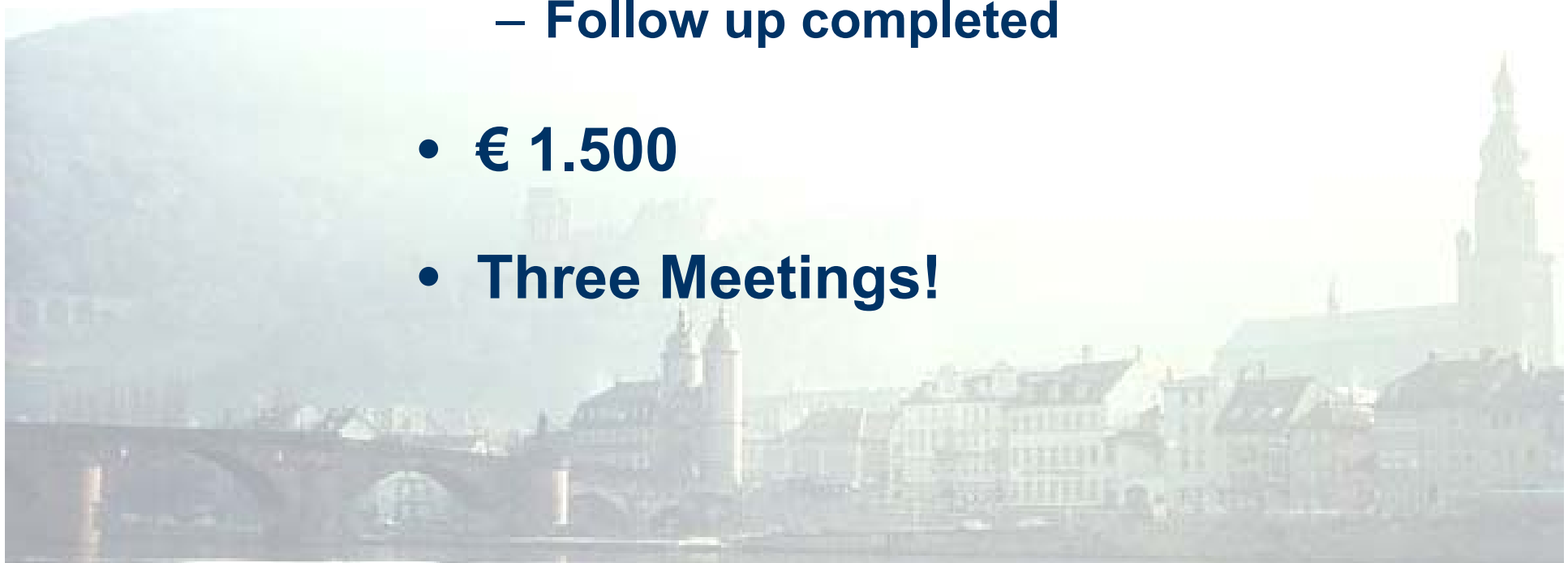


Charité Virchow, Berlin
Bochum
Freiburg
Heidelberg
Köln, Augustinerinnen
Leipzig
Liverpool
Ljubljana
Mannheim
Munich - LMU
Munich - TU
Regensburg
Würzburg



Funding for Centres

- **Each patient**
 - Randomized
 - Treated
 - Documented
 - Follow up completed
- **€ 1.500**
- **Three Meetings!**





Milestones



- **Submission of grant proposal** 11/2007
- **Full application** 05/2008
- **Funding obtained (DFG)** 12/2008
- **Ethical approval** 04/2009
- **International registration (ISRCTN)** 04/2009
- **Investigators Meeting** 05/2009
- **First patient** 05/2009
- **Last patient** 07/2011
- **Last follow up** 07/2013
- **Results available** 01/2014



Contact

www.chropac-trial.eu

Trial coordinator:

Prof. Dr. med. Christoph M. Seiler, MSc
christoph.seiler@med.uni-heidelberg.de

Project manager:

Dr. Alexandra Moreno-Borchart
Tel.: +49 (6221) 56 37728
alexandra.morenoborchart@med.uni-heidelberg.de

Project assistant:

Elena Buss
Tel.: +49 (6221) 56 6540
elena1.buss@med.uni-heidelberg.de

ChroPac