Study Centre of the German Surgical Society (SDGC)

Newsletter 5 – 03/2008

Topics

Editorial

Dear members of the DISPACT study group,

Thank to you all for an outstanding recruitment! We are proud to inform you all that the 200th patient has been entered the DISPACT trial on February 22nd.

We are better than expected and already focus the interim analysis. An interim analysis will be performed when 224 patients with left-resection of the pancreas are achieved. According to documentation so far, about 15 % of all randomised patients have not undergone per protocol treatment. Thus, approximately 260 randomised patients will be needed. We hope to achieve this goal with you later this year.

Four new participating centres have joined the group, two of them having already randomised a patient. Thanks a lot!

On behalf of the Steering Committee

Christoph M. Seiler

Markus Diener

Inga Rossion

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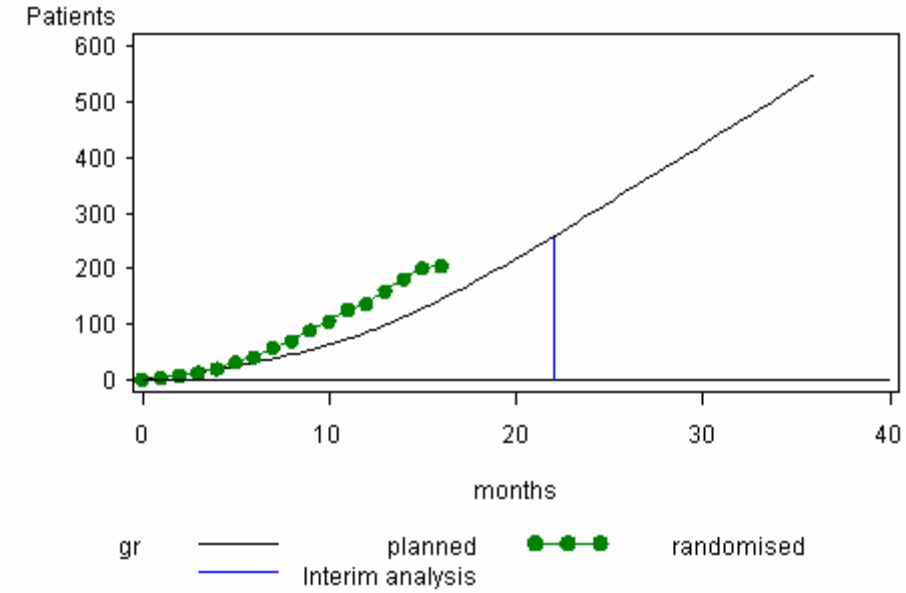
Patient recruitment

Patient enrolment is progressing well and still is slightly higher than the pre-planned recruitment plan. At present, 207 patients are randomised. Up to date information on randomisation status can be found on page one of the DISPACT website www.dispact.de

DISPACT: Recruitment plan and Reality



Participating Centres

To date, 20 trial centres are activated, 17 of them having already randomised patients.

We welcome as new participating centres:

Sanaklinikum Berlin-Lichtenberg,
Bochum St Josefskrankenhaus,
Dresden-Friedrichstadt,
Marburg University Hospital.

Other participating centres are:

Amsterdam, Berlin Charité Mitte, Berlin Charité Virchow, Gent, Freiburg, Heidelberg, Homburg, Köln-Merheim, Ljubljana, Mannheim, München-Großhadern, München-Rechts der Isar, Regensburg, Verona, Würzburg, Wuppertal.

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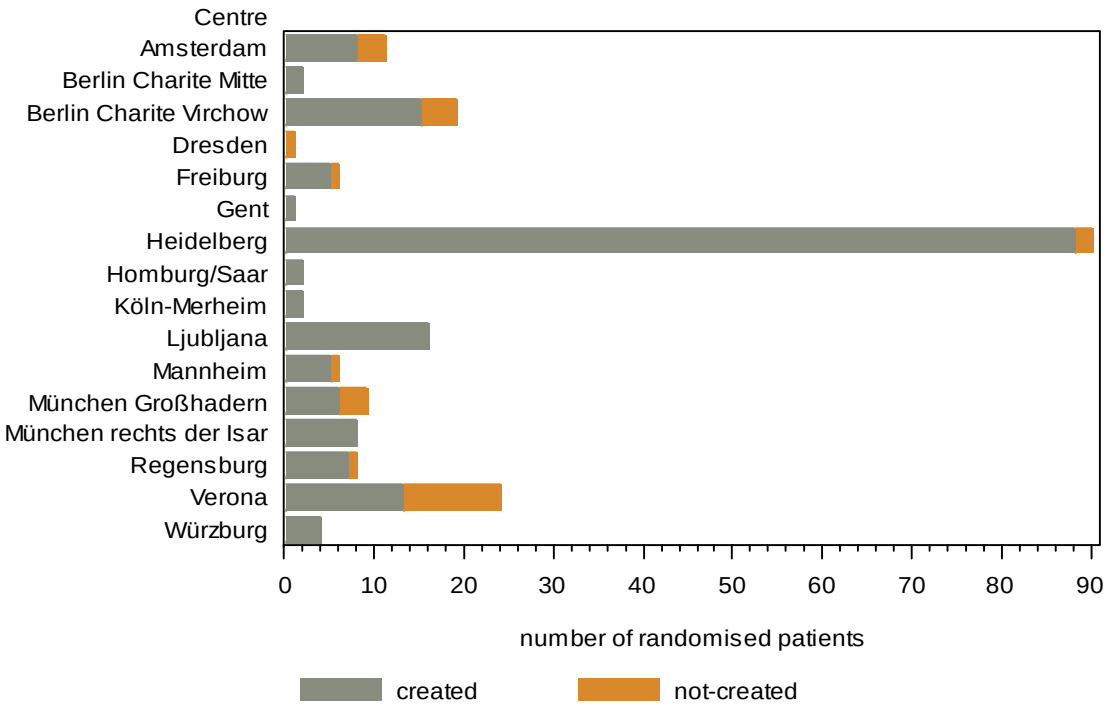
Documentation

Overall documentation is quite good with an average of 80 %, some centres demonstrating excellent records with close to 100 %. We will keep you informed on this issue once a month and offer support, if you need anything.

The first round of queries has been send out and successfully answered including eCRF completion or correction by most centres.

DISPACT: Patients documented in Macro



Blinding and Outcome Assessment

Blinding is a very effective instrument to prevent bias in clinical trials but remains difficult to implement in surgical trials. As it is impossible to blind the surgeon, it was chosen for the DISPACT trial to maintain a double blinding of the patient and the outcome assessor. The investigator responsible for the task of outcome assessment should be listed in the log of staff in the investigator site file.

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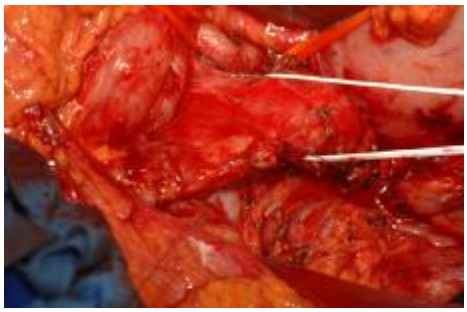
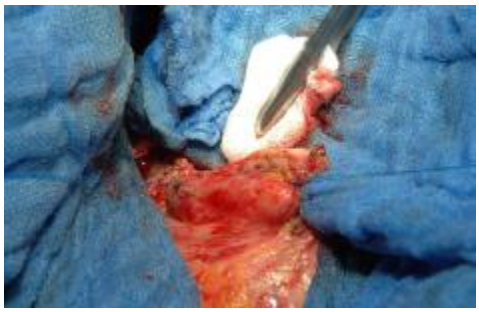
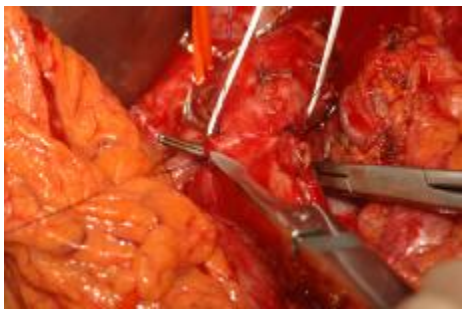
Dispactrial

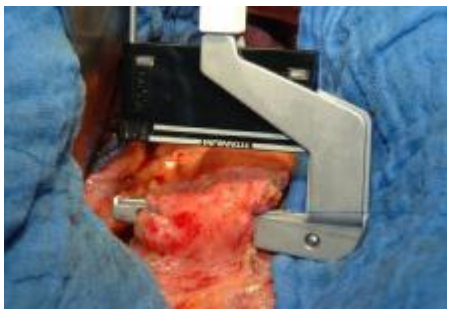
Photo-upload

On January 30th, the data verification committee reviewed all intra-operative photos that were uploaded between November 2007 and January 2008. Blinded against centre, patient ID and randomised procedure, the committee was able to evaluate photos from about 60 patients. The photos were overall of excellent quality, thus it was possible to identify the surgical procedure in a large number of cases (see example below).









For some patients only one or two photos existed, which makes evaluation of protocol adherence difficult. Please make an effort to take three photos for each intervention: resection site, execution of resection and closed pancreatic remnant.

eCRF: Changes in Primary Endpoint

Some of you might have already noticed that we have replaced one question in Visit No 3 'Assessment of the primary endpoint' concerning the grading of pancreatic fistula. The reason being that the old question "Was the management of the patient changed if amylase activity in drain fluid on or after day three until day seven after left resection was three times higher than the normal range?" could not be answered correctly, if there was no fistula. With the new question "Did the patient develop a transient fistula with no clinical impact?" it is now possible to document any fistula grade A (transient fistula with no clinical impact) according to the definition of Bassi et al even if amylase content in drain fluid is normal or only moderately elevated.

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Monitoring – change of staff

Sonja Wittkus, who has done excellent work accompanying the DISPACT trial centres during the first year, is leaving us. We wish her good luck for her future career. At the same time, we are very happy that two experienced monitors are taking over: Barbara Hügle-Dörr and Marion Kiel from KKS-Heidelberg have already introduced themselves to their respective centres. If you have any questions, feel free to contact them:

Adress for both:
Koordinierungszentrum für Klinische Studien (KKS) Universitätsklinikum
Voßstrasse 2 / Gebäude 4410
69115 Heidelberg
www.kks-hd.de

Dr. rer. nat. Barbara Hügle-Dörr
Tel.: ++49(0)6221-56 34512
Fax : ++49(0)6221-56 1950
Barbara.Huegle-Doerr@med.uni-heidelberg.de

Marion Kiel (Dipl. oec. troph. (FH)
Tel.: ++49 (0)6221 56 38257
Fax: ++49 (0)6221 56 33508
Marion.Kiel@med.uni-heidelberg.de

With kind regards from Heidelberg

The DISPACT Steering Committee and the DISPACT Team at the SDGC