Study Centre of the German Surgical Society (SDGC)

Newsletter 13_July 2009

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Editorial

Dear DISPACT trial group,

We are happy to see that recruitment for DISPACT trial has been extraordinary successful and the group has been able to randomize 450 patients in 2 ½ years.

Thus, we are now about 6 months ahead of schedule and hope that we can keep this advance until the end of the trial. Please have a look at the new time schedule at the end of this letter.

We are proud to see that the DISPACT trial group has demonstrated such a great performance in this large international surgical trial using modern technology software and internet tools for randomization, documentation and quality assurance.

Thank you for your outstanding commitment !

On behalf of the Steering Committee

Christoph M. Seiler

Markus K. Diener

Inga Rossion

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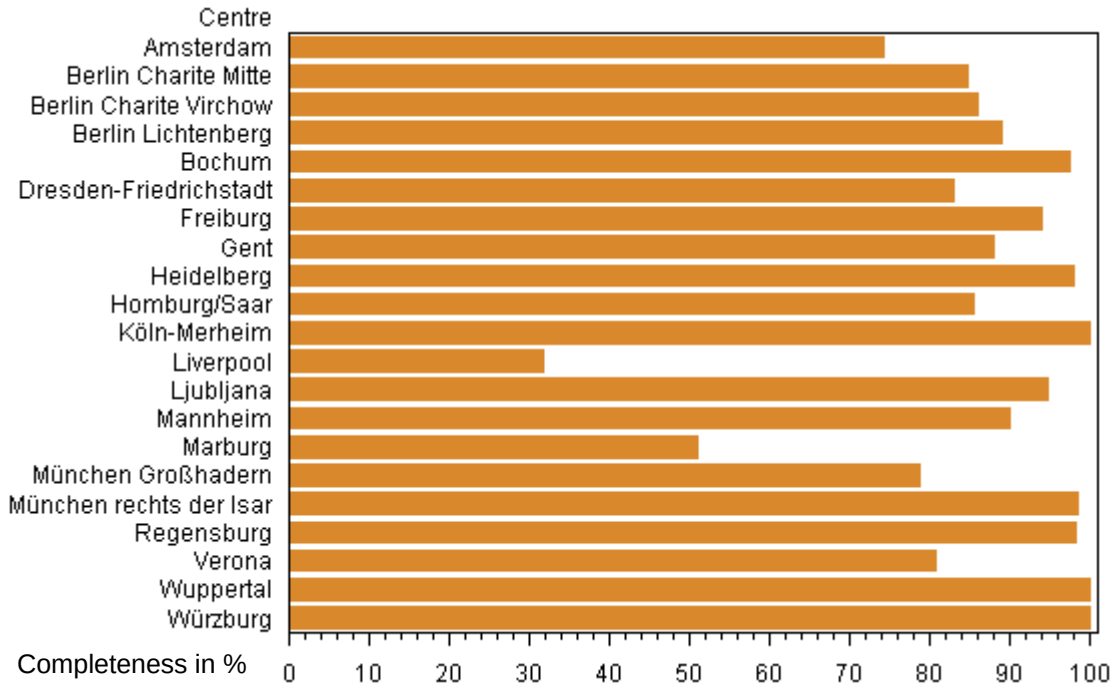
Documentation

Documentation has always been excellent for the DISPACT trial during the entire recruitment period. At present, overall completeness of documentation is at 90 %, which means that some centres have already reached 100 % completeness (see details for each trial centre below).



Information on the primary endpoint pancreatic fistula on post-operative day 7 is available for all patients now. If a randomized patient has been operated on, but no left resection was performed, then please document this on visit 2 "operation" and fill out the end-of-study form. Trial centres should try to have their documentation up-to-date in MACRO as soon as possible, so that the primary endpoint can be evaluated soon (see timelines).

Follow-up

To date, some follow-up data is missing. In order to have all data complete for closure of the patient file in MACRO, follow-up should be documented without delay as soon as the last follow-up has taken place.

Please check all your patients regularly, so that you will not miss any visits. This is particularly important for visit 6 after 12 months. You may start ahead of time to contact your patient. The exact date is calculated as day of distal resection plus 12 months. However, we allow a tolerance for conducting visit 6 with a time window leading from 4 weeks before the exact date until 4 weeks after this date.

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Monitoring

All centres will have had at least one on site monitoring visit by the end of the study. High recruiting centres will have a number of visits as frequency depends on the number of patients recruited by each trial centre. Main focus will be put on the source data verification for all endpoint relevant data.

As soon as all data have been completely documented in MACRO - including 12-months follow-up - the monitoring will verify the patient file in MACRO. In case there are any questions or missing data discrepancies are raised and the investigator is asked to respond directly to these questions and put the answers into the record in MACRO.

Getting ready for close-out

Queries

are generated whenever there is a need for it and should be answered within a time frame of 2 weeks. All open queries must be answered accurately. The data manager will check if all queries haven been answered and will verify that there are no more open queries.

Discrepancies

are raised by the monitor who is the one to confirm that all discrepancies are answered.

Electronic signature

If these conditions are fulfilled, the patient record concerned may be closed in MACRO. Please note that the investigator has to sign with her/his electronic signature each individual patient file in MACRO.

Centre close-out

When all patients of a trial centre are completely documented including 12-months follow-up, the centre should prepare for close-out. For this purpose, you will need to check whether all documents and lists in your investigator site file are up-to-date and complete: signed informed consent forms of all patients, curriculum vitae of investigators involved in the trial, screening list, recruitment list etc. For close-out, you will be handed out a separate check list by the monitor. In case you have any questions, have them ready for the monitoring visit or mail them in advance to your monitor.

Case payments

As soon as a patient has been completely documented in MACRO including 12 months follow-up and signature of the file, you may bill us for your case payments.

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Photo upload

This month, the Surgical Review Board has evaluated almost all remaining photos. Thanks to the centres for making an effort and uploading your photos last minute. There are only a few centres which have not responded to our call. Make sure to complete the upload of your surgical photos.

For the analysis of the trial population it is – of course - crucial to know, if a patient has received the trial treatment (stapler closure or hand-suture) or not. If you have not done the photo documentation, please specify this in the eCRF visit 2.

Timelines for analysis

As recruitment is ahead of time, we count on being ahead of time, too, with documentation, statistical analysis and publication. This timetable will be adapted according to the progress made during the next steps.

July 3, 2009	last patient in
until August 2009	data input in MACRO for primary endpoint
until September 2009	monitoring visits and queries
October 2009	data base closure for primary endpoint
November 2009	results primary endpoint
July 2010	end of follow-up
October 2010	trial centres to return all open queries *
November 2010	data base closure
December 2010	final results
January 2011	investigator's meeting
April 2011	publication of results

Looking Forward – New trials!

The discussion about closure of the pancreatic remnant after left resection needs further research. We plan a further trial to compare the winner of Dispact with closure of the remnant with seromuscular surface (stomach or small bowel). We hope the group will stay together and invite all members to develop the next trial with us. Please let us know your interest per mail to christoph.seiler@med.uni-heidelberg.de.

Many of you already participate in the ChroPac trial comparing duodenum preserving pancreatic head resection versus pancreatico-dudoenectomy in patients with chronic pancreatitis. Please visit our homepage: http://www.chropac-trial.eu/.

With kind regards from Heidelberg

The DISPACT Steering Committee and the DISPACT Team at the SDGC