Study Centre of the German Surgical Society (SDGC)

Newsletter 7 – June 2008

Topics

Editorial

Dear members of the DISPACT study group,

Facing the DISPACT interim analysis patient recruitment has been successfully completed and Randomizer.at was stopped on June 19th, 2008.

Although the number needed to randomize had to be adjusted by the trial statistician to 282 patients, the trial group was still able to reach this goal before the end of June, which is at least 3 months ahead of schedule.

Congratulations to all trial centres for this great performance!

We hope that we can proceed quickly to the next step, so that results will be in as fast as possible. This issue of the newsletter will inform you on time-lines, important tasks and preparations for the interim analysis.

On behalf of the Steering Committee

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Patient numbers and sample size calculations

224 patients evaluable for trial intervention (e.g. patients that have received a left resection) and data for the primary endpoint are needed in order to receive a valid result from this interim analysis (see Newsletter 5 - May 2008 for more details).

Due to pre-operative randomization, it was difficult to calculate the number of patients needed to randomize in order to obtain 224 patients for interim analysis. The drop-out rate for inoperable patients seems to be quite different among centres. Also, the rate of patients who have not received any trial intervention for other reasons seems to vary from one trial centre to the other. This is for example the case, if patients had to undergo a total pancreatectomy, an enucleation, or a central resection instead of a distal resection of the pancreas. In order to compensate for these patients lost for interim analysis, the number needed to randomize was recalculated by our statistician to 282 patients.

Timelines for interim analysis

June 19, 2008	**randomization was stopped**
July 5, 2008	**trial centres to put all data in MACRO (Visit 1 – 3 with primary endpoint including AE, end of study for all patients who terminated study prematurely, SAE reports)**
July 5, 2008	**trial centres to return all open queries ***
July 19, 2008	**data base closure**
July 26, 2008	**results of analysis to be sent to independent Data Safety and Monitoring Board for assessment and guidance for the Steering Committee. Decision on how to continue (stop for clear result in favour of one technique, go on for initial planned or adjusted sample size, stop for futility)**

*** It is possible that new queries are raised on new data recently entered in MACRO for interim analysis. In order to make sure that all data are complete and correct, these queries will need to be answered within the same time frame.**

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Patients documented in MACRO

Centre	Completeness[%]
Amsterdam	90.0
Berlin Charite Mitte	100.0
Berlin Charite Virchow	89.0
Berlin-Lichtenberg	73.5
Bochum St. Josef	25.0
Dresden-Friedrichstadt	50.0
Freiburg	100.0
Gent	62.5
Heidelberg	93.3
Homburg Saar	100.0
Köln-Merheim	100.0
Ljubljana	100.0
Mannheim	84.7
Marburg	62.5
München LMU - Großhadern	60.7
München TU – rechts der Isar	69.0
Regensburg	88.3
Verona	93.5
Würzburg	80.5

In this table, only relevant data for interim analysis is accounted for (Visit 1-3 with primary endpoint, AE, end of study if premature). Overall completeness is not bad, for some centres it is already excellent. We are convinced that it will be feasible to obtain 100 % within 3 weeks.

Photo Review

The Data Verification Committee has anonymously reviewed intra-operative photos of more than 70 patients. Quality of photos was excellent. Thanks to all centres for taking these great photos and doing a good job in uploading them. There were very few photos that could not be evaluated.

We hope that you will all help to get the data in and stay prepared to restart randomization as soon as possible if we are going to continue.
With kind regards from Heidelberg

The DISPACT Steering Committee and the DISPACT Team at the SDGC