Study Centre of the German Surgical Society (SDGC)

Newsletter 10 / December 2008

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Editorial

Dear colleagues in DISPACT trial centres,

2008 has been a successful year for DISPACT trial. All centres have demonstrated a great performance in recruiting patients for the trial and did an excellent job in documenting for interim analysis.

This year, 170 patients have been randomized in spite of an interruption of almost 3 months. If we continue at the same speed, the recruitment goal of 450 patients may be achieved within the previewed time frame by the end of next year.

Warmest greetings to everyone and a Merry Christmas !

On behalf of the Steering Committee


Christoph M. Seiler


Markus K. Diener


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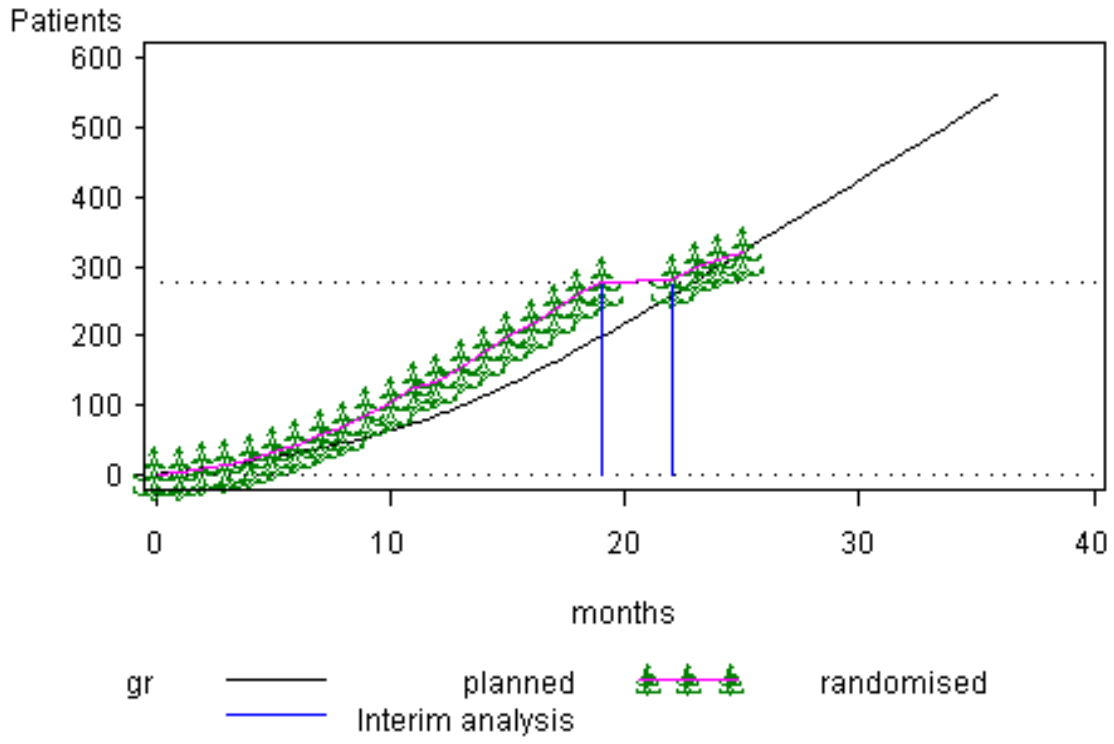
Trial centres

9 trial centres have already recruited more than 10 patients, 4 of them more than 20 patients thus being able to gain a lot of expertise on trial specific procedures. We would like all centres to include patients regularly, so that this learning effect is not lost during the course of the trial. This is especially important for those centres not having restarted randomization after interim analysis. Make an effort to keep up with the trial!

Welcome to Wuppertal who has randomized its first patient. 2 new centres are also preparing to join the group in January.

Patient recruitment

As you can see below, at the end of this year the set-actual comparison of patient recruitment shows an especially nice curve, generated by our biostatician.



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Dispactrial

Surgical intervention

From intra-operative photos and source data verification by monitors, we are receiving important feedback on actual surgical procedures in all trial centres. To be compliant with the protocol, distal pancreas should be resected with surgical scalpels only. Please note, that no electric knives are allowed.

In the hand-suture group, the pancreatic remnant is closed with slowly absorbable monofilament thread in USP 4/0 or 5/0 using single stitched or running suture. Non-absorbable sutures are neither required nor permitted. Ligation of the pancreatic duct should be separately stitched. For hemostasis, no additional covering e.g. collagen fleece coated with thrombin and fibrin glue is allowed. In the stapler group, single stitches are tolerated in case of bleeding but no complete suturing.

Suture materials and staplers are furnished to all centres. Surgical interventions are to be carried out according to the trial protocol page 21 ff and the operation manual.

Primary endpoint

On day 7 after distal resection of the pancreas, the primary endpoint pancreatic fistula is documented following the consensus definition by Bassi et al. (see trial protocol). Grading is based on clinical symptoms and content of total amylase in drained fluid compared to serum level. Drains should be left in place until day 3 post-intervention and amylase concentration should be analyzed between day 3 and 7.
Elevated values of pancreatic amylase or lipase are not valid for this definition, even though they may indicate substantial loss of pancreatic fluid.

1. Definition of pancreatic fistula:

   Drain output of any measurable volume of fluid on or after postoperative day 3 with an amylase content greater than 3 times the serum amylase activity.

   AND / OR

2. Clinical Grading:

   Grade A: "Transient fistula" with no clinical impact.

   Grade B: Requires change in management
   (e.g. partial or total parenteral nutrition; leukocytosis, interventional drainage, antibiotics, somatostatin analogues, extended hospital stay, readmission)

   Grade C: Major change in clinical management
   (e.g. total parenteral nutrition, somatostatin analogues, i.v. antibiotics, sepsis, organ dysfunction, intervention, revision of anastomosis, and delay in hospital discharge)

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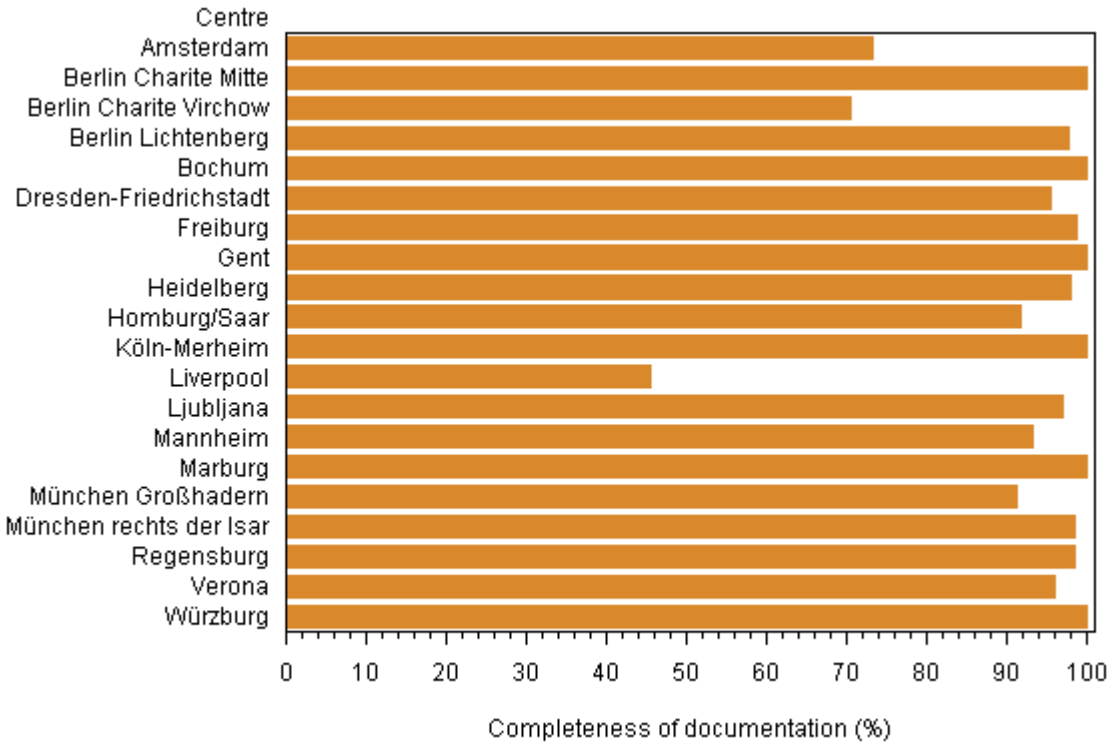
Documentation

Documentation is still excellent with an overall mean of 93 % completeness.



12-months follow-up

All centres are asked to complete documentation for their patients. About 150 patients have reached their 12-months follow-up already. Templates for structured telephone interview should be used as source document for visit 5 (30-days) and visit 6 (12-months). Most important are endpoint relevant data on survival, serious adverse events (SAE) and morbidity.

The data manager will check, whether documentation is complete and all queries are answered. If the monitor indicates no more discrepancies, data management will then confirm end of study for each patient. Last, the MACRO file needs to be signed by the investigator. After this, the file will be locked and no further changes will be possible.

For every patient with confirmed end of study and complete documentation, trial centres may receive the remunerations as stipulated in the contract.