

Newsletter 3/2007



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Editorial

Dear members of the DISPACT study group,

we are happy to inform you that the 100th patient has just been randomised into the DISPACT trial this mid-september! Thank you to all centres for their recruitment efforts, which have given a very successful start to DISPACT.

Thus, DISPACT trial has passed from springtime to summer and is really flourishing now. Most of the centres have now randomised their first patient(s) and have made their experience in implementing the trial at their site. At present, we are entering the consolidating phase of the DISPACT trial with two main objectives before us: to go on with patient recruitment at the established level and at - the same time - to begin with electronic documentation of all randomised patients in a timely manner. If each centre realises these objectives at its own rhythm, then we will reach our goal step by step.

On behalf of the Steering Committee

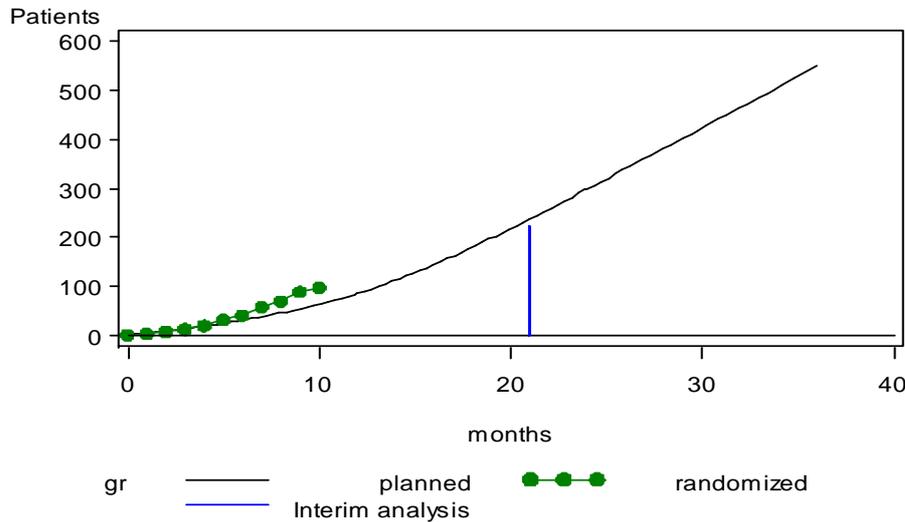
Christoph M. Seiler, MD

Markus K. Diener, MD

PATIENT RECRUITMENT AND PREPARATIONS OF PARTICIPATING CENTRES

Patient enrolment is progressing very nicely and still following recruitment plan with 100 patients randomised at present.

DISPACT: Recruitment plan and Reality



PARTICIPATING CENTRES

To date, 14 trial centres are activated, 11 of them having already randomised patients.

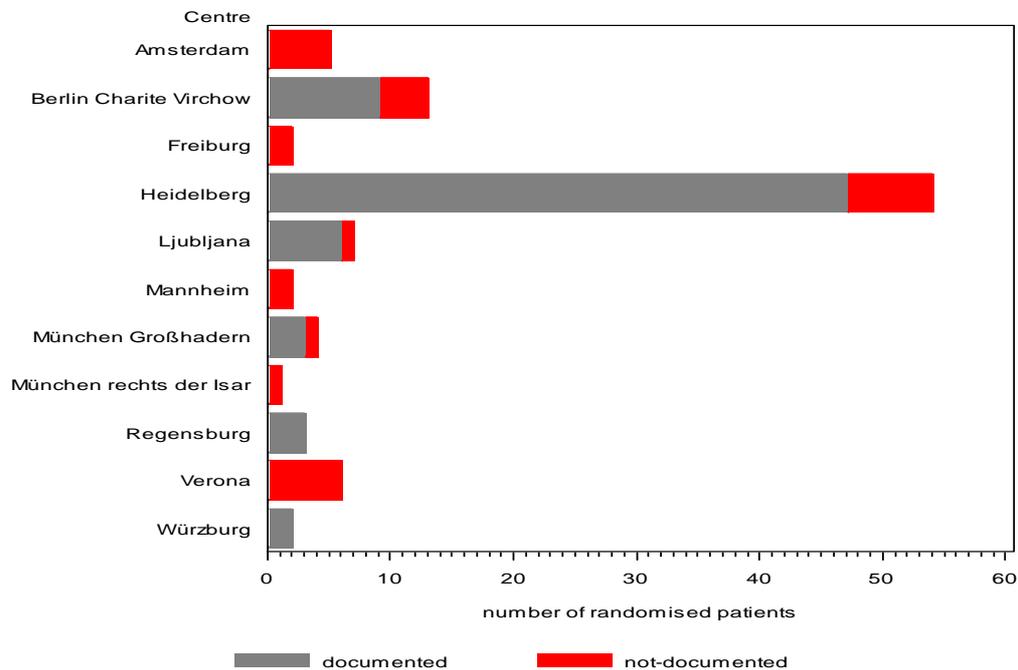
Activated centres are: Amsterdam, Berlin Charité Mitte, Berlin Charité Virchow, Freiburg, Heidelberg, Homburg, Köln-Merheim, Ljubljana, Mannheim, München-Großhadern, München-Rechts der Isar, Regensburg, Verona, Würzburg. A number of further sites should be ready soon for activation.

ELECTRONIC DOCUMENTATION

Based on the randomisation lists, electronic documentation of each patient should start with visit 1 (screening and patient selection criteria) and visit 2 (operation) within a delay of 14 days. The data management is preparing a surveillance service reminding you of any patient, who has not been documented within 4 weeks of randomisation. This is done in cooperation with the monitor, who will make an appointment with each centre after the complete hospital stay of your first patient has been documented including visit 4 (discharge). Note that all operated patients need to be treated and documented according to the trial protocol. In case it was impossible to perform a left-resection, the operated patient still has to be included and documented for the intent-to-treat procedure. If no surgical intervention was performed at all, then please fill out visit 1 (screening), explain the reason on visit 2 (operation) and fill out the end of study form.

eCRF: DOCUMENTATION PLAN AND PRESENT SITUATION

DISPACT: Patients documented in eCRF



DOUBLE-BLINDING

The surgical technique used is supposed to be kept blinded during the DISPACT trial. Of course, it is impossible to blind the surgeon. We therefore propose to not mention the technique applied for distal pancreatectomy in the operating report, but to rather use a standard wording like "distal pancreatectomy was performed according to randomisation within the DISPACT trial". In order to be able to perform an objective assessment of primary endpoints, both the patient and the outcome assessor are blinded for the resection technique used. It is suggested to have the assessment carried out by an investigator or study nurse independent from the operating team.

LOOKING FORWARD

We are very keen to hear from you about how the trial is going on in your centres. So please do not hesitate to ask your questions, inform us about things happening at your site or tell us about any issues worth knowing for the trial group. We will make an effort to give you every support you might need.

With kind regards from Heidelberg

The DISPACT Steering Committee and the DISPACT Team at the SDGC