Study Centre of the German Surgical Society (SDGC)

Newsletter 9 - 10/2008

Topics

Editorial

Dear colleagues in DISPACT trial centres,

We now have passed an important step with the steering committee's decision to continue the DISPACT trial. There will be no changes compared to the original plan as described in the trial protocol. Thus, randomization will continue until 450 patients will be included.

Thanks to everybody for the excellent performance which has enabled us to carry out a valid interim-analysis.

On behalf of the Steering Committee

Christoph M. Seiler

Markus Diener

Inga Rossion

Interim Analysis

Of course, we were all very interested to know the results of DISPACT interim analysis. However, neither the steering committee nor the principal investigator is informed about the results.

In conformity with biometrical guidelines, the analysis was carried out by an independent statistician and sent directly to the Data Safety Monitoring Board. The DSMB then gave the recommendation to continue DISPACT trial without disclosure of results.

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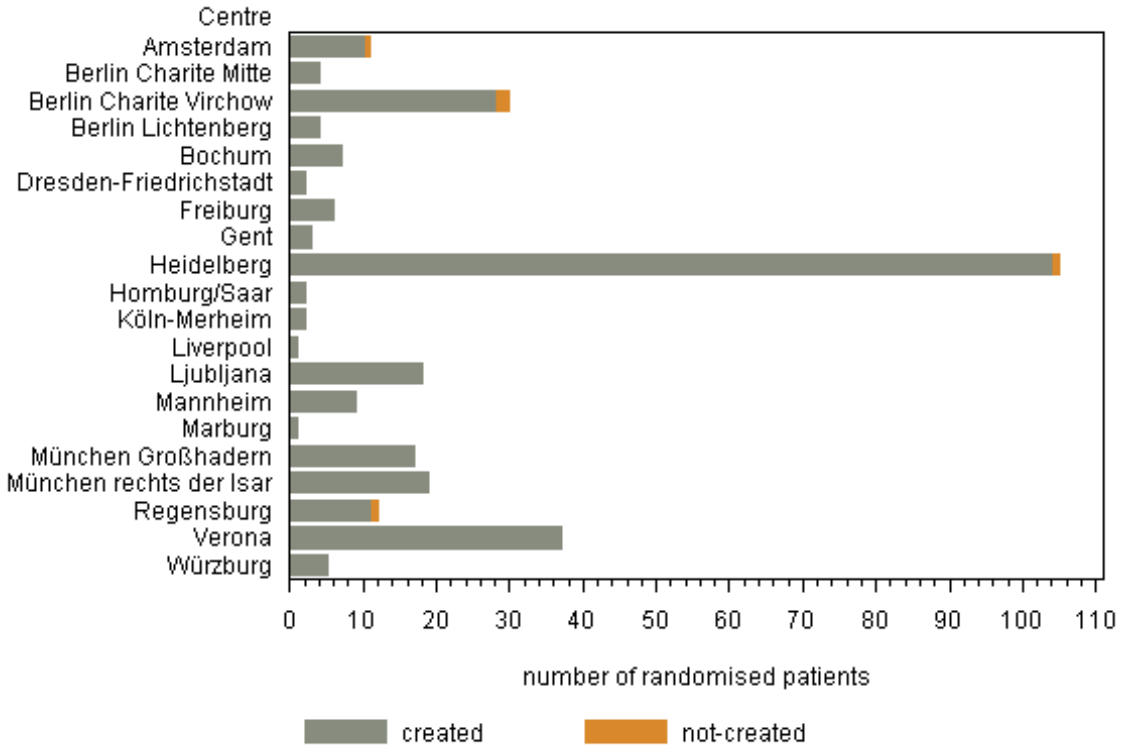
Documentation and case payments

Documentation for interim analysis was really excellent. Thanks to all centres for completing endpoint relevant data in time.



Centres now need to answer all remaining queries so that documentation may be closed. Once the data management has reported "no open queries" and the monitor has confirmed "no open questions in MACRO", then the individual patient record in MACRO should be signed by the investigator.
As soon as a patient has been completely documented in MACRO including 12 months follow-up, you may bill us for your case payments.

Lessons learned : informed consent and patient information

Informed consent is a highly sensitive issue for ethics committees and compliance with Good Clinical Practice. Great emphasis is attributed to this issue by the monitor. Non-compliance may result in major protocol violation. As a consequence, no trial intervention may be carried out and no patient data may be used for trial purposes.
Keeping the original signed informed consent form in the investigator site file is an absolute necessity. No copies are accepted for this purpose. Please keep in mind that date and signature of informed consent need to be filled out by the patient him/herself.

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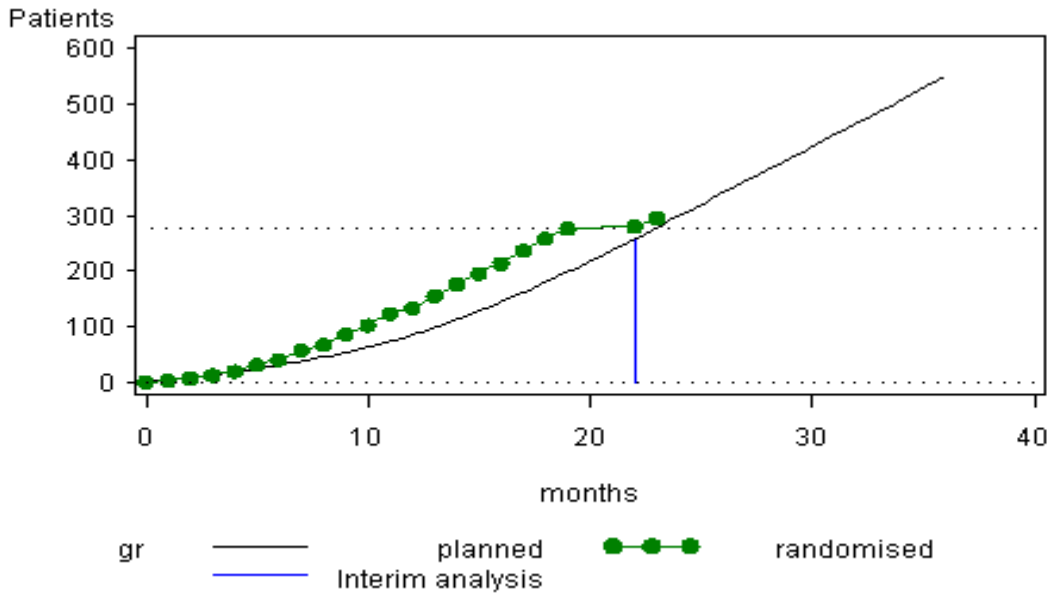
Present Status of DISPACT trial

Since the restart of randomisation 22 new patients have been included by 8 trial centres. We hope that all centres will join in again and take up randomisation, especially those who have not yet randomised 10 patients. We welcome Liverpool as new centre who has joined the group after having to remove quite a number of obstacles.



Looking forward - timelines for continuation of DISPACT trial

September 4th 2008	restart of randomization
December 2009	last patient in
December 2010	end of follow-up
June 2011	data base closure
December 2012	final results

With kind regards from Heidelberg

The DISPACT Steering Committee and the DISPACT Team at the SDGC