Newsletter 01-12/2021

TOPICS

EDITORIAL

Dear members of the DISPACT-2 trial group,

With this first newsletter we warmly welcome all participating trial sites and would like to update you about the status of the DISPACT-2 trial.

First, we would like to inform you that Prof. Pascal Probst has left the Department of General, Visceral and Transplantation Surgery in Heidelberg and will not be able to act as coordinating investigator any more. From now on, Dr. Rosa Klotz will be in charge of the DISPACT-2 trial as coordinating investigator. She is a surgeon from the Heidelberg University Hospital where she has gained experience in pancreatic surgery and the conduction of multicentre randomized controlled trials.

In addition, a lot of work has been done since our successful first investigator meeting in January and we are very thankful for your commitment in the past months. The trial centre Homburg was able to recruit the first patient with randomization on April 26th 2021 (Heidelberg: August 13th 2020). Until now 39 patients were randomized by 8 out of 16 initiated trial sites. We hope that the remaining already initiated trial centres will also be able to start recruitment very soon. You will find more details in the paragraph "Participating Trial Sites and Initiation" and "Recruitment Status" below.

With kind regards

Your coordinating investigator Dr. med. Rosa Klotz & the DISPACT-2 trial team

PARTICIPATING TRIAL SITES and INITIATION

In total 21 trial sites will participate in the DISPACT-2 trial and 16 sites have already been initiated until today (see table below).

Trial site	Initiation
Ostalb Klinikum Aalen Department of Surgery I – General and Visceral Surgery	initiated
University Hospital RWTH Aachen Department of General, Visceral and Transplant Surgery	initiated
University Hospital Bonn Department of General, Visceral, Thoracic and Vascular Surgery	initiated
Helios-Amper Klinikum Dachau Department of General, Visceral, Thoracic and Oncological Surgery	initiated
University Hospital Carl Gustav Carus of the Technical University Dresden Department of Visceral, Thoracic and Vascular Surgery	initiated
University Hospital Erlangen Department of Surgery – General, Visceral and Specialized Visceral Surgery	initiated
University Hospital Frankfurt Department of General, Visceral and Transplant Surgery	not yet initiated
University Medical Center Freiburg Department of General and Visceral Surgery	initiated
University Hospital Halle Department of Visceral, Vascular and Endocrine Surgery	initiated
Heidelberg University Hospital Department of General, Visceral and Transplant Surgery	initiated
University Hospital of the Saarland, Homburg Department of General, Visceral, Vascular and Paediatric Surgery	initiated
Klinikum Köln-Merheim Department of Visceral, Tumor, Transplant and Vascular Surgery	initiated
Royal Liverpool University Hospital Department of General Surgery	not yet initiated
University Medical Centre Ljubljana Department of Abdominal Surgery	not yet initiated
University Medical Centre Schleswig-Holstein (Campus Lübeck) Department of General Surgery	initiated
University Hospital Marburg Department of Visceral, Thoracic and Vascular Surgery	initiated
Klinikum Memmingen Department of General, Visceral, Vascular and Thoracic Surgery	initiated
University Hospital of the Ludwig-Maximilian-University of Munich Department of General, Visceral, Transplantation, Vascular and Thoracic Surgery	not yet initiated
Klinikum rechts der Isaar of the Technical University of Munich Department of Surgery	initiated
Klinikum Stuttgart – Katharinenhospital Department of General and Visceral Surgery	not yet initiated
University Hospital Ulm Department of General and Visceral Surgery	initiated

RECRUITMENT STATUS

Up to this point of time, 39 patients have been randomized by the following 8 trial sites within 16 months: Aachen, Bonn, Dresden, Erlangen, Halle, Heidelberg, Homburg, Lübeck. This corresponds to a

lower recruitment rate per month as expected (2.4 vs. 12.25 patients). To achieve our final recruitment target of 294 patients, which should be allocated to the trial within 24 months, we have to catch up recruitment (see figure below).

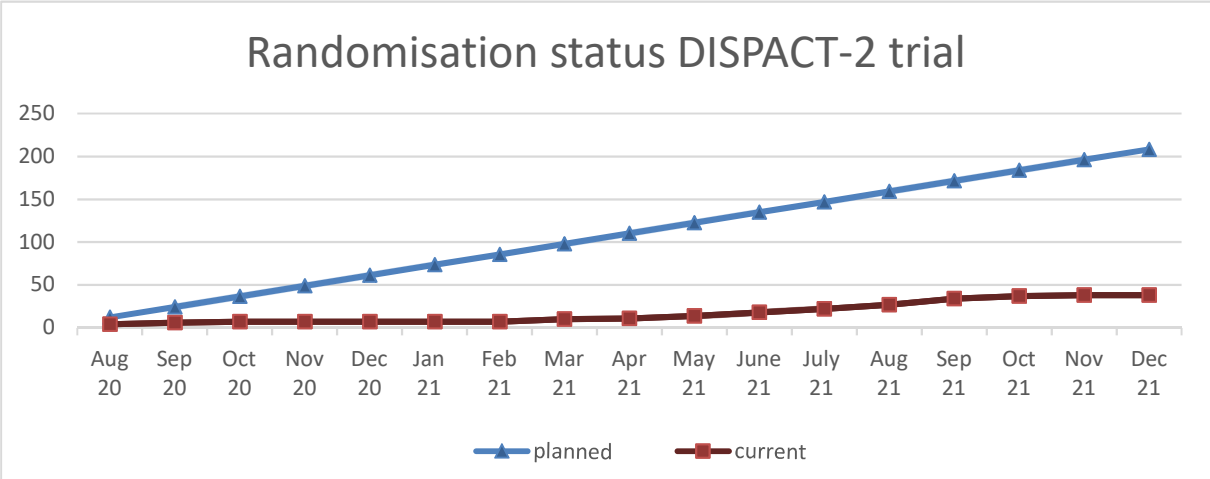

Figure 1: Planned and current recruitment by December 13, 2021.

Overall 15 out of 21 trial sites fulfil the requirements for recruitment and can now include patients. Therefore, we would like to ask you for your active support in achieving the recruitment goal by enrolment of patients in the DISPACT-2 trial. If any help is needed concerning the enrolment of patients or the implementation of the trial in your site please don't hesitate to contact our project management team (see "Trial Team" below).

AMENDMENT to CHANGE the COORDINATING INVESTIGATOR

Due to the change of the coordinating investigator of the DISPACT-2 trial, the amendment documents were submitted to the independent ethics committee of the Medical Faculty, University Hospital Heidelberg on November 02, 2021. As soon as we receive the approval of the ethics committee in Heidelberg, we will submit the required documents for the amendment to the responsible ethics committees of your sites.

INCLUSION of TURKISH-SPEAKING PATIENTS

We would like to inform you that the Ethics Committee of the Medical Faculty of Heidelberg has approved the Turkish trial documents (informed consent, EORTC QLQ-C30/PAN26) so that turkish-speakingpatients can now be included in the DISPACT-2 trial. If there are Turkish-speaking investigators available in your trial site and you are interested in including turkish-speaking patients in the DISPACT-2 trial, please don't hesitate to contact our project management or monitoring team so that we can submit the relevant documents to the responsible ethics committees.

TIPS for CONDUCTING the DISPACT-2 TRIAL

For enrolment of the first patients at your trial site we would like to give some advices and tips regarding several aspects in conducting the DISPACT-2 trial according to the current protocol version 2.2.

Tip 1: Registration of patients as trial subjects in your site

If you document in the electronic/hospital patient chart, that the patient is included in our DISPACT-2 trial, this will inform the non-trial team in your institution. This may help the clinical team to support the trial, even if the personnel are not member of the trial team. For this purpose please document each patient who is enroled in the DISPACT-2 trial as a patient in a clinical trial in the electronic clinical database of your clinic or in his/her hospital patient chart. Documentation of the date when the patient has given his informed consent to the trial, would be exemplary.

Tip 2: Completion of the Patient information and informed consent

During the informed consent process please make sure/double check that all the following fields are properly and handwritten completed:

- Information that must be completed by the investigator taking consent:
  - name (2x)
  - question field: If there are no questions please note this, e.g. “Der Patient hatte keine weiteren Fragen./The patient had no further questions”.
  - name of the patient’s family doctor: Please cross out this field if the patient does not want to reveal the family doctor’s name.
  - question about the restriction on patient data use for other research purposes: Please cross out this field if the patient does not restrict the further use of his/her data.
- Information that must be completed by the patient:
  - name
  - date of birth
  - signature
  - location
  - date
  - question about the consent to the evaluation of the existing patient data when withdrawing from the trial

Tip 3: Correct randomisation of patients

The randomization of your enrolled patient should be done after screening and informed consent one week to one day before surgery using the web-based randomisation tool "randomizer.at" (https://www.randomizer.at/random/login). Please make sure to give all data:

- The **screening number** that matches the screening number on the screening and enrolment log needs to be filled in the field **Subject-ID**.
- The **year of birth** of the patient needs to be given in the comment field.

Incorrect entries (screening number, year of birth) can be corrected afterwards. The corresponding information about a correction should be sent to the data management (see "Trial Team" below).

Tip 4: Blinding of the outcome assessor

The outcome assessor is blinded during the final classification of complications according to Clavien-Dindo. In this case, the source documents (hospital patient charts and other study files) must not give the responsible investigator any information about the treatment group (MIDP or ODP). Please also note that the outcome assessor must not have access to the randomizer.at and the eCRF (REDCap).

Tip 5: Completion of the worksheets "Surgeon's expertise"

The study document "Surgeon's expertise" should be completed and signed by the surgeons prior to the start of the DISPACT-2 trial. Please note that the number of operations performed by a surgeon may increase during the course of the trial and the question of the surgeon's experience (number of MIDPs and ODPs) is categorized into categories (1-20, 21-50, 51-100, >100) in the eCRF (visit 2 "Surgeon's expertise"). Surgeon's expertise should be checked after the patient's operation. If a surgeon falls into the higher category, he/she should be asked again about the experience. His/her experience should then be properly documented. Updated information should be documented directly on the corresponding document "Surgeon's expertise" with the current date and signature or in the case of a question about the experience by e-mail, this e-mail should be printed out and attached to the "Surgeon's expertise" document.

Tip 6: Use of the paper printout of the eCRF as a worksheet for documentation in the eCRF

Please note that the paper printout of the eCRF, which can be used as worksheets for the study-specific data collection, summarizes several visits, e.g. visits 3 and 4. Therefore, before carrying out the visit, you should check which parameters are required for the specific visit (in comparison with the eCRF), because not all parameters have to be recorded in every visit. To clarify this point, the paper printout of the eCRF will be completed with the visit numbers in the header and made available to you.

TRIAL TEAM

If there are any questions or you need any assistance feel free to contact us:

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Project management	
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