AGENDA

Phone Conference: 30 Oct 2014, 08:30-9:30h (CET)
Phone number: +49-30-23328920 (PIN: 0004)

Diagnostic Imaging Strategies for Patients with Stable Chest Pain and Intermediate Risk of Coronary Artery Disease: Comparative Effectiveness Research of Existing Technologies (DISCHARGE)

DISCHARGE Coordinator and Work Package Leaders: P01 Charité Prof. Marc Dewey, Adriane Napp (MSc), Robert Haase (MD), Prof. Jacqueline Müller-Nordhorn; P24 INSERM Dr. Christine Kubiak; P26 BIOEF Dr. Iñaki Gutiérrez-Ibarluzea; P27 CVUT Prof. Vladimir Rogalewicz; P28 UKJ Prof. Peter Schlattmann

DISCHARGE Clinical Sites: P02 MUI Prof. Gudrun Feuchtner; P03 UZA Prof. Rodrigo Salgador; P04 FN Motol Prof. David Zemanek; P05 REGIONH Prof. Klaus Kofoed; P06 ALB; P07 ULEI Prof. Matthias Gutberlet; P08 SE Prof. Pál Maurovich-Horvat; P 09 SET; P10 NUID UCD; P11 UNICA; P12 UNIROMA Prof. Marco Francone; P13 PSKUS; P14 Prof. LSMU Prof. Gintare Sakalyte; P15 WSS Ewa Zdunczyk, Jaroslaw Bitt; P16 CHVNG/E Prof. Nuno Bettencourt; P17 CAM Dr. Sebastian Condrea, Prof. Theodora Benedek; P18 IKVBV; P19 ICS-HUVH; P21 KSSG; P22 Glasgow; P23 AUHT

DISCHARGE non-clinical sites: P01 Charité Nina Rieckmann (BSPH), Corinna Meier-Windhorst (KKS)

DISCHARGE Boards and Committees: EAB Harold Sox; DSMB Tim Friede

Schedule

1) Welcome by Prof. Dewey (5 min.)

2) Implementation Steps (10 min.) Rodrigo Salgado was invited to join the development of the by the project coordination
   a) Finalizing Pilot Study
   b) IRB approval and Certification of Cardiac CT readers
   c) eCRF and Database Testing

3) CT Management (15 min.)
   a) Management Flow Chart (5 min.)
   b) Ischemia Threshold (5 min.)
   c) Which Imaging Ischemia Tests are allowed for Patient Management? (5 min.)

4) CT Reading (25 min.)
   a) 10-Step-Guide to successful cardiac CT (10 min.)
   b) Contrast injection protocol (5 min.)
      i) Maximal Scan Duration of Oldest Scanners
      ii) 12 Versus 10 as Constant in the Formula for Calculating the Total Amount of Contrast Agent to be Used in a DISCHARGE Patient
   c) Plaque Characterization by CT (5 min.)
   d) Non-cardiac Findings on CT (5 min.)

Administration by Adriane Napp (5 min.)

Nr.	Issues	Outcomes	ID
1	**Welcome**	Change of pretest probability 10 – 60%	MD
2	**Implementation Steps**		AN
	a) Finalizing Pilot Study 3 CT test patients /3 ICA test patients	Prepare anonymized image data for 3 ICA and 3 CT (according to 10 step guide) patients and send either per CD to Charité or wait until upload server is available	
	b) IRB approval and Certification of Cardiac CT Readers Mail 10.10 3 changes pretest, ivabradine and heart rate lowering med between 55-60 except ivabradine. Did you submit amendment?	- Status overview: 60% of the clinical sites have IRB approval and 70% started with the pilot study. -Mail with all relevant IRB information sent on 10.10.2014. Clinical sites asked to contact their IRB for the amendment. - Missing information about cardiac CT readers will be sent to the clinical sites	
	c) eCRF and Database testing deadline presets	Missing presets can be sent by 6.11.2014	
3	**CT Management**		
	a) Management flow chart a. Information: Cross-over ICA to CT allowed but not wanted	Study coordinator stressed the importance of avoiding cross-over from ICA to CT, no comments or objections from the participants.	MD
	b) Ischemia threshold a. 10 % okay for all different imaging stress tests?	After a brief discussion, it was decided that the ISCHEMIA study thresholds for relevant myocardial ischemia will be used in DISCHARGE (will be in the eCRF). Skipping stress testing in patients with significant stenosis in CTA does not mean patient dropout, though with respects to the contracts of the European commission and the study protocol it should be avoided that no imaging ischemia test is done in 1- and 2-VD.	MD
	c) Which imaging tests are allowed for patient management (discussion)?	Stress echocardiography, Stress-MRI, SPECT and PET are allowed. Each site should specify the best locally available stress test if not done yet. This test should be performed as standard in the majority of patients. Commonly, patients are not able to reach sufficient stress levels through exercise alone. Therefore, additional application of Adenosine is recommended for the best locally available imaging ischemia test.	MD

		Discussion with nuclear medicine specialists for SPECT and PET and with MR and Echo specialists at the local sites is recommended now.	
	d) IVUS and FFR rates at clinical sites	Please submit your current IVUS and FFR rates before making PCI decision in clinical practice and discuss the use with the local cardiologists. The IVUS and FFR use and rate in the ICA arm of DISCHARGE should not change from your current practice. Project Management will send an Excel sheet.	MD
4	**CT Reading**		
	a) 10 Step-Guide a. Information: minor changes i. Better use capsule than spray (nitro) ii. 19 segments model b. Missing presets	The changes to the 10 step guide were presented, there were no comments or objections. Project coordination stressed the importance of submitting the missing data for the presets.	RH
	b) Contrast injection protocol a. What is the maximal scan duration of oldest scanners? (needs to be changes in table in 10 Step Guide) b. 12 versus 10 as constant in the contrast agent amount formula (discussion)	a. Maximal scan duration is 10 sec. b. 10 is preferred as the constant in the contrast agent amount formula to reduce the amount of contrast agent used. The revised 10 step guide will be provided.	RH
	c) Plaque characterization document	The plaque characterization document is finished and Rodrigo Salgado was asked to join the CRF development process by the project coordination. All participants were invited to participate in the CRF development and may contact Marc Dewey in case they want to participate in any of the CRF working groups (do not hesitate, now is the time to influence the CRFs, in 4 weeks they will be final!). Gudrun Feuchtner suggested implementing Plaque analysis according to research by Nakazato et al. Pál Maurovich-Horvat will investigate whether adjustments to the CRF are reasonable. The question of practicability for clinical sites was raised and should be the main focus.	RH
	d) Non cardiac findings	The flow chart for long nodules based on lung rads is still in development in collaboration with Jonathan Dodd. Study coordination pointed out, that tracking patients with pulmonary nodules, and ensuring that the flow chart recommendations are met in	RH

		the majority of patients, is an ethical obligation, mandatory according to the study protocol and important for secondary outcome analysis. The flow chart is a suggested guideline, patient management can be modified to specific patients scenarios, for instance patients with signs of infection and possible pneumonia can receive short-term follow-up CT in 2 weeks after treatment to show disappearance of lesions. Further examples of non-cardiac findings will be discussed in the next telephone conference.	
5	**Administration**		AN
	a) Consortium Agreement and Clinical Site b) New clinical partner c) consortium agreement version 2 e) Suggestions of telephone conference to participants d,e) Other	a) Consortium Agreement version 1 will be turned into Consortium Agreement version 2 and a clinical site contract. Contents of clinical site contract: - clinical sites are self-responsible - recruiting patients into DISCHARGE and studies with the same/similar inclusion criteria (e.g. ISCHEMIA) are not allowed. If there are ongoing studies DISCHARGE has to be prioritised. Patients outside the 10-60% pretest probability of DISCHARGE for inclusion may be included in other studies but not patients within the 10-60% range. - CT perfusion and CT FFR are not allowed in DISCHARGE. b) Information that P20 OSTERGOTLANDS has left DISCHARGE because they realised that they cannot pursue the clinical study. Partners can suggest new clinical sites in November. Contract Amendment Process with the European Commission will start ca. December, 2014 d) Harold Sox (Chair of the External Advisory Board) suggested providing the sites with a 'corelab doctor hotline' to resolve urgent clinical management and image interpretation questions from the clinical sites with Charité core lab personnel. The study coordinator will provide sites with this non-public phone number which will be available during the day (except weekends). e) Tim Friede asked for more information about the negative predictive values of CT for the	

		probability, will be provided by project management. f) study coordinator suggested new telephone conferences: - in three weeks a meeting with the interventional cardiologists of all clinical sites to discuss how to use information derived from CTA for best intervention planning in the cath lab - in approx. four weeks an all partner meeting prior to start of the study. Steering Committee phone conference immediately afterwards. Dates will be announced by project management	