



News Letter 1

Dresden, October 22, 2014

Dear National Coordinators and Local Investigators of PROBESE,

Dear Friends,

The first 18 patients of PROBESE have been randomized! Four months after the official call for centers we are proud to announce: PROBESE started out amazingly. The European Society of Anaesthesiology (ESA - Funding partner), as well as the European Society for Perioperative Care of the Obese Patient (ESPCOP) and different regional Societies of Anesthesiology (e.g. Germany, Italy) have endorsed our study. Until now, more than eighty centers confirmed participation, and National coordinators from different countries worldwide are involved in recruiting study centers. While the PROBESE collaboration is continuously growing, we would like to share some news regarding this endeavor with you.

National and local coordinators

At the end of this newsletter you will find a list of all national coordinators and local investigators as well as their current status regarding review board (IRB) application and on the Call-for-Centers (CFC) forms. Please contact probese@peg-dresden.de if you identify incorrectness in this list.

Funding and Insurance issues

We must emphasize that PROBESE is an investigator-initiated trial. At current, there is no financial support. Therefore, case fees or other form of financial compensation for study related costs cannot be granted. Importantly, centers must provide insurance for their own study patients. In case of doubt, you can discuss country-specific regulations with the national and the international coordinators.

New study protocol version 2.4.2

Many IRBs have revised the study protocol thoroughly, suggesting improvements that do not interfere with approval in other centers. Changes in the protocol are summarized on the very first pages of the new version 2.4.2. Briefly, we skipped interim analyses, improved the description of



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the statistical methods and the reporting of adverse events (appendix v.), and updated the study sheet (Appendix iv.). The new file “Study protocol_v2.4.2_PROBESE_with changes.pdf” should be used by centers that have not submitted the protocol for IRB application so far. **If you have already submitted a previous protocol version (2.4.1 or older) to your IRB, don’t panic: changes in the protocol have a formal character and can be submitted as amendments after approval.**

Homepage

We would like to draw your attention to the study homepage (www.peg-dresden.de/probese). Here you can find updated files. As soon as national coordinators receive final ethical approval, translated versions of the study documents will be uploaded to that homepage. Certainly, you can also obtain all documents directly from the trial coordinator.

Applications for sub-studies are welcome!

We strongly encourage you to apply for sub-studies within PROBESE at the steering committee. We tried to pave the way by including different facultative outcome measures *per se* (e.g. spirometry), but please feel free to expand the knowledge that we may gain from this study. You may also consider networking with other PROBESE centers to increase numbers of patients for your sub-study. Applications will be considered on a first-in, first-served basis. Once approved by the steering committee, they will be announced at the study homepage. Please be aware that results from sub-studies can only be made public in any form (lectures, abstracts, conference contributions, papers etc) after the main study has been published and upon consent of the steering committee.

Further steps

As soon as you send us a copy of IRB approval for your center, you will receive two sets of logins into the PROBESE electronic case report form (eCRF): One login for pre- and intraoperative data entry (includes access to randomization), and a further login data set for pre- and postoperative data entry. **Please note: Because of blinding, the person receiving the pre/intraoperative login is not allowed to use the pre/postoperative login and vice versa.** To ensure blinding, there must be at least two assessors per patient at your center available.



Table: Summary of National Coordinators and attending Local Investigators for PROBESE.

If you identify incorrectness regarding your names or current IRB status, please contact probese@peg-dresden.de. Centers that have not sent the Call-for-centers form until now are kindly requested to fill it out and send it to the above mentioned email address.

Country	National coordinator	Co-worker	Local Investigator	Co-worker	City	IRB status	CFC
Austria	Markstaller, Klaus	Kabon, Barbara			Vienna	preparing submission	yes
Australia and New Zealand	Van Haren, Frank				Canberra	preparing submission	no
	Robertson, SimonJ				Canberra	preparing submission	no
Bahrain	Koshy, Lena				Busaiteen	preparing submission	yes
Belgium	de Baerdemaeker, Luc		Mulier, Jan		Ghent	preparing submission	yes
					Bruges	preparing submission	yes
Brazil	Sá Malbouisson, Luiz Marcelo	Prior Caltabeloti, Fabíola			São Paulo	preparing submission	no
	Ary Serpa Neto				São Paulo	preparing submission	no
			Do Nascimento Júnior, Paulo		São Paulo	preparing submission	no
			Da Silva Júnior, João Manoel		São Paulo	preparing submission	no
			Dos Reis Falcão, Luiz Fernando		São Paulo	preparing submission	no
Canada	Laffey, Jon				Toronto	preparing submission	no
Chile	Altermatt, Fernando				Santiago de Chile	preparing submission	no
	Pedemonte, Juan Cristobal				Santiago de Chile	preparing submission	no
			Florez, Jorge		Santiago de Chile	preparing submission	no
Germany	Wrigge, Hermann				Leipzig	preparing submission	yes
			Bluth, Thomas		Dresden	Recruiting	yes
			Treschan, Tanja		Duesseldorf	Approved	yes
			Laufenberg-Feldmann, Rita	Mauff, Susanne	Mainz	Approved	yes
			Rossaint, Rolf	Stevanovic, Anna	Aachen	Approved	yes
			Busch, Cornelius		Heidelberg	preparing submission	no
			Bergmann, Lars		Bochum	preparing submission	no
			Jungwirth, B		Munich	preparing submission	no
			Schilling, Thomas		Magdeburg	preparing submission	yes
			Bone, Hans-Georg		Recklinghausen	preparing submission	yes
Greece	Papaioannou, Alexandra				Heraklion	preparing submission	yes
Hungary	Bobek, Ilona				Budapest	preparing submission	no
Isreal	Matot, Idit	Cattan, Anat			Tel Aviv	preparing submission	no



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Italy	Aurilio, Caterina		Napoli	submitted	no	
		Ballotta, Andrea	Milan	preparing submission	no	
		Brunetto, Bruno	Savona	preparing submission	no	
		Carboni, Adrea	Aosta	preparing submission	no	
		Cataldo, Rita	Rome	preparing submission	yes	
		Cinnella, Gilda	Foggia	preparing submission	no	
		Cortegiani, Andrea	Palermo	preparing submission	yes	
		Cortese, Gerardo	Turin	preparing submission	no	
		Di Salvo, Claudio	Pisa	preparing submission	no	
		Fiore, Gilberto	Moncalieri	preparing submission	no	
		Fossali, Tommaso	Milan	preparing submission	no	
		Gatta, Alessandro	Romagna	preparing submission	no	
		Giovannitti, Alfonso	Bologna	preparing submission	no	
		Incalcaterra, Pietro	Savigliano	preparing submission	no	
		Marenghi, Cristina	Milan	preparing submission	yes	
		Moise, Gabriella	Milan	preparing submission	no	
		Mokini, Zirajir	Monza	preparing submission	no	
		Mosca, Alessandro	Cagnazzi, Elena	Brescia	preparing submission	yes
		Nosedo, Guido	Lecco	preparing submission	no	
		Pavoni, Vittorio	Firenze	preparing submission	no	
		Pelosi, Pelosi	Genoa	preparing submission	no	
		Petrini, Flavia	Chieti	preparing submission	no	
		Piazza, Ornella	Baronissi	preparing submission	yes	
		Puscio, Daniela	Lecce	preparing submission	no	
		Rojatti, Marco	Udine	preparing submission	no	
		Severgnini, Paolo	Varese	preparing submission	no	
		Spadaro, Savino	Ferrara	preparing submission	yes	
		Taccone, Paolo	Milan	preparing submission	no	
		Vettoretto, Katuscia	Brescia	preparing submission	no	
		Piazza, Ornella	Baronissi	preparing submission	no	
Poland	Gaszynski, Thomas		Lodz	preparing submission	yes	
		Mozanski, Marcin	Warsaw	preparing submission	yes	



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for Surgery in OBESE Patients

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Portugal	Abelha, Fernando			Porto	submitted	no
		Machado, Humberto	Aguiar, Jose	Porto	Recruiting	yes
		Manuel Seixas	Pinto, Fernando	Coimbra	preparing submission	no
		Castro, Diogo Sousa		Santa Maria da Feira	preparing submission	no
Romania	Godoroja, Daniela			Bucharest	preparing submission	yes
Saudi Arabia	Elgendy, Hamed			Makka	preparing submission	yes
Spain	Canet, Jaume			Badalona	preparing submission	no
		Suárez de la Rica, Alejandro		Madrid	preparing submission	yes
		Ripolles, Javier	Martinez Hurtado, Eugenio	Madrid	preparing submission	yes
		Sánchez Merchante, Miriam		Madrid	preparing submission	yes
		Ferrando, Carlos		Valencia	preparing submission	yes
		Granel Gil, Manuel		Valencia	preparing submission	yes
		Unzueta, Carmen		Barcelona	preparing submission	no
Switzerland	Licker, Marc-Joseph			Geneva	submitted	no
The Netherlands	Hollmann, Markus			Amsterdam	preparing submission	no
	Sabrine Hemmes			Amsterdam	preparing submission	no
		Zonneveldt, Harry	Kievit, Pieter	Hoorn	preparing submission	yes
Turkey	Senturk, Mert			Istanbul	preparing submission	no
		Erdogan, Dilek		Istanbul	preparing submission	yes
		Erdivanli, Basar		Rize	preparing submission	yes
		Dinc, Bora		Antalya	preparing submission	yes
		Aksun, Murat		Izmir	preparing submission	no
		Corman, Pelin		Istanbul	preparing submission	yes
Ukraine	Vorotyntsev, Sergiy			Zaporozhye	preparing submission	yes
United Kingdom	Mills, Gary			Sheffield	preparing submission	no
United States	Sprung, Juraj			Rochester, Minnesota	preparing submission	no
		Vidal Melo, Marcos	Jiang, Ning	Boston	preparing submission	yes
		Obal, Detlef		Louisville	preparing submission	no
		Brull, Sorin		Jacksonville, Florida	preparing submission	no
		Fernandez-Bustamante, Ana	Moine, Pierre	Aurora, Colorado	preparing submission	no
		Lee, Jae-Woo	Haight, Matthew	San Francisco	preparing submission	no
		Nair, Singh		New York	Approved	no
		Cohen, Edmond		New York	preparing submission	no



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Yours sincerely,

Thomas Bluth, MD
Trial Coordinator
Department of Anesthesiology
and Intensive Care Medicine
University Hospital Dresden
Technische Universität Dresden
Dresden, Germany

Marcelo Gama de Abreu, MD, PhD
Principle Investigator
Department of Anesthesiology
and Intensive Care Medicine
University Hospital Dresden
Technische Universität Dresden
Dresden, Germany

Ary Serpa Neto, MD, MSc, PhD
Department of Intensive Care
Academic Medical Center
University of Amsterdam
Amsterdam, The Netherlands

Marcus J. Schultz, MD, PhD
Department of Intensive Care
Academic Medical Center
University of Amsterdam
Amsterdam, The Netherlands

Sabrine N. T. Hemmes, MD
Department of Intensive Care
and Anesthesiology
Academic Medical Center
University of Amsterdam
Amsterdam, The Netherlands

Paolo Pelosi, MD
Department of Surgical Sciences
And Integrated Diagnostics
University of Genoa
Genoa, Italy