Steering Committee News Letter 1

Dresden, September 19, 2013

Dear members of the steering committee,
Dear friends,

I would like to inform you about the progress of our VIPS Trial.

1. Trial Status

At present, 6 centers have approval from their IRB

- University Hospital Dresden, Germany
- Hospital de la Santa Creu i Sant Pau, Barcelona, Spain
- University Hospital in Reus, Spain
- Medical University of Vienna Vienna, Austria
- IRCCS San Martino Hospital, University of Genoa, Italy
- Academic Medical Center at the University of Amsterdam, Amsterdam, The Netherlands

Centers waiting for ethics committee approval:

- Saint Eloi University Hospital and Montpellier School of Medicine, Montpellier, France
- St Thomas' Hospital, London, United Kingdom
- Hospital Sírio-Libânes, Intensive Care Unit, São Paulo, Brazil
- Hospital Copa D'Or, Rio de Janeiro, Brazil

If your center is still waiting for approval, could you give me a short update to your status?

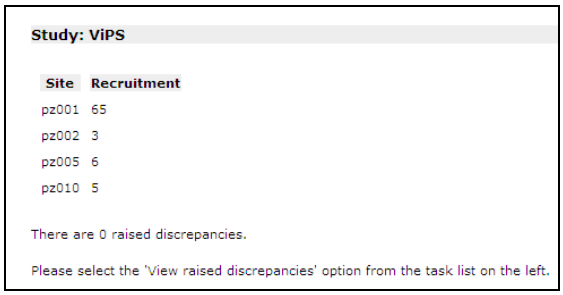
2. Publication of the Study Protocol

We submitted our Study protocol for publication in „Trials". As the journal will not publish our manuscript as long as all listed centers have ethics committee approval, we decided to list

only the approved centers. This fact does not influence the authorship! All initially listed authors are still on the paper.

3. Database entry – Screened Patients

If you log in the study database, on the first screen, you will see the centers and the number of patients per center. Possibly, some of you wondered, why center pz001 has more patients than other centers.



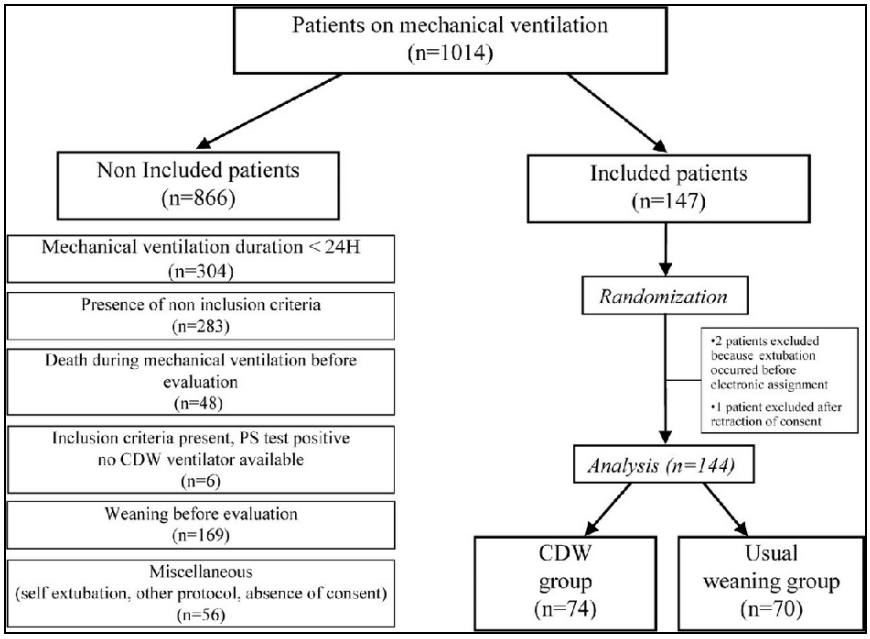
Study: ViPS

Site	Recruitment
pz001	65
pz002	3
pz005	6
pz010	5

There are 0 raised discrepancies.

Please select the 'View raised discrepancies' option from the task list on the left.

Pz001 65 does not mean that we randomized 65 patients. In fact, we screened 65 patients – some oft them have been randomized (approx. 20 patients). For later publication, it is important to register all screened patients in the database. In other words: <u>all patients that are on mechanical ventilation longer than 24 hours should be registered</u>. A typical flow chart from a published study shows specific information about the patients that have not been included - look at the picture below (left row):



Lellouche et al.; A multicenter randomized trial of computer-driven protocolized weaning from mechanical ventilation.

Am J Respir Crit Care Med. 2006 Oct 15;174(8):894-900.

For the VIPS Trial, we want to know how many patients have been ventilated for more than 24 hours, which of inclusion/exclusion criteria have been met..

If you find problems with the database entry, please contact me. I will be happy to help you!

4. Database entry – Adverse events

If one of your study patients encounters any adverse or severe adverse event, please use the „Adverse Events“ Tab in our database. Every month, all registered events are transmitted to our SAE manager (Dr. Sabrine Hemmes – thanks for your participation!) who processes the cases. In case of a severe adverse event which is related to the study or may be related to the study - I would be happy to get a separate email from you within 24 hours of occurence.

Please let me know if you have any addition questions or suggestions.

Thank you all for your special effort and participation!

Best regards, Thomas Kiss