Steering Committee News Letter 2

Dresden, March 24, 2014

Dear members of the steering committee,
Dear friends,

1. Trial Status

In total, 62 Patients have been included in the ViPS Trial (228 Patients are needed!). The following table shows you the recruited patients per center (effective 24.03.2014):

Center	Number of Subjects (screened+randomized)	Number of randomized patients	Date of last Patient randomization
Dresden	94	29	12.03.2014
Vienna	8	4	18.02.2014
Barcelona	40	7	02.10.2013
Genua	38	13	24.03.2014
Reus	103	9	07.02.2014

This table suggests that a significant number of patients must be screened until a patient is included and randomized. Please don't forget to screen all patients that are on controlled mechanical ventilation for more than 24 hours in your ICU – journals require namely CONSORT diagrams showing the number of screened patients with reason for non-enclosure. For further details, please have a look in Newsletter Nr. 1!

I also want to inform you that Amsterdam (Fabienne Simonis, Marcus Schultz) received positive ethics committee approval and will start to recruit patients shortly.

2. Trial Webpage

The official ViPS Homepage is available here: http://www.peg-dresden.de/vips. You can find the frequently asked questions, documents and parts of the study protocol on the website. If you have any documents to upload or any questions – please inform me to publish it on the website for all other collaborators.

3. Publication of the Study Protocol

The Study Protocol has been published in the „Trials“ journal and is downloadable via http://www.ncbi.nlm.nih.gov/pubmed/24176188 or http://www.trialsjournal.com/content/14/1/363.

4. Adverse Events

Our drug safety monitoring board (DSMB) is composed of our SAE manager Sabrine Hemmes, Amsterdam and two DSMB members (Rupert Pearse, London & Rolf Rossaint, Aachen). Sabrine will assess all events and will report them if necessary to the DSMB for review. Please enter your adverse events in the database, especially if they are life threatening, lead to death or prolong hospitalization. All related or possibly related events and all unexpected events should be reported within 24 hours to Sabrine (s.hemmes@amc.uva.nl). This topic has already been described in Newsletter Nr. 1. Below you will find two pictures on how to enter Adverse Events in the database.

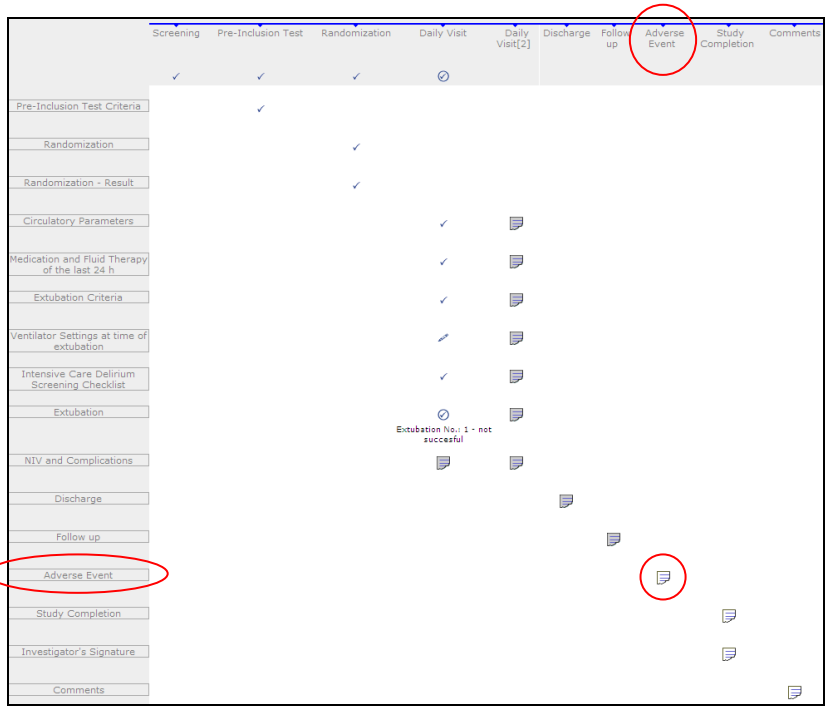
Please let me know if you have any addition questions or suggestions.

Thank you for your good work so far!

Best wishes from Dresden

Thomas Kiss

Standard subject overview:



The Adverse Event mask: