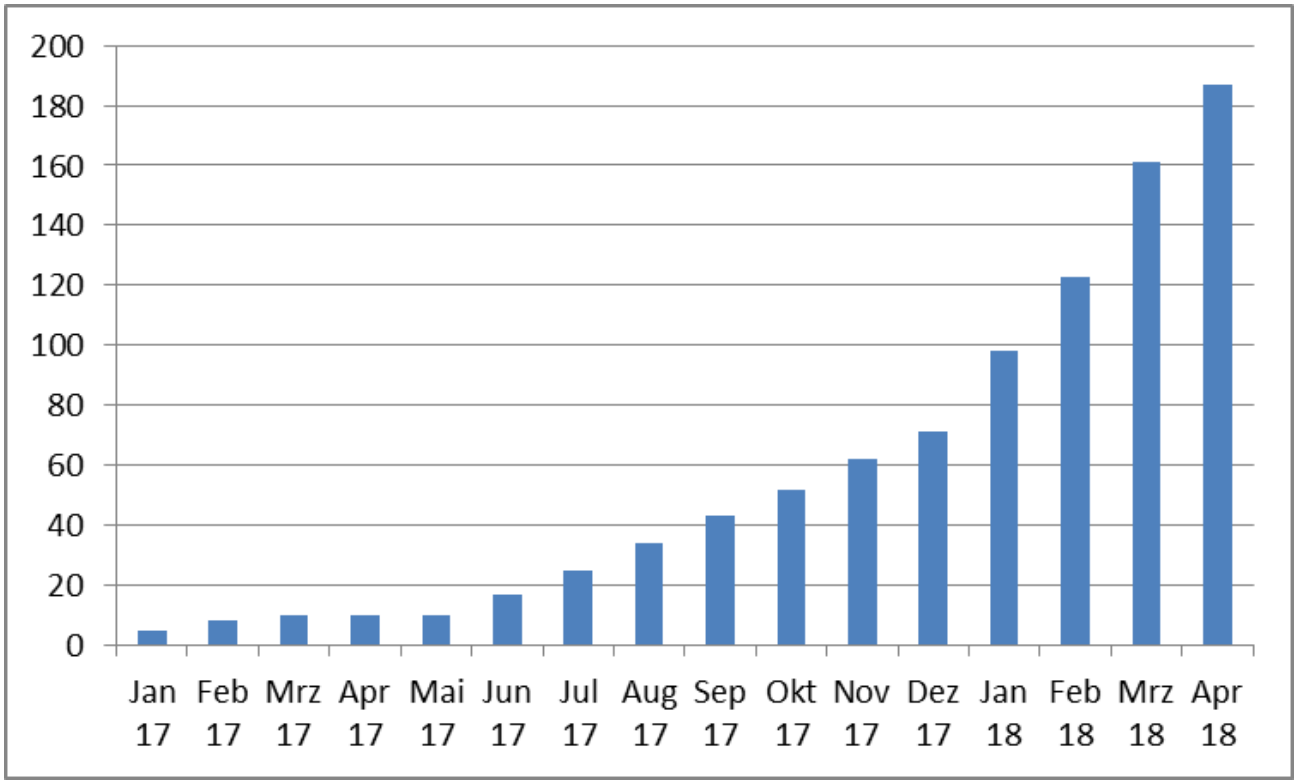
PROTHOR Newsletter 2/2018

Dresden, April 27, 2018

Dear National Coordinators and Local Investigators of PROTHOR,

Three months have elapsed since the last Newsletter. I want to give you a short overview on the general progress. We have 25 centers actively working on the study (and the number of centers is still increasing), we have 189 randomized patients in the study (effective 25.04.2018).

Overview of randomized patients over time



Overview of the records per center (including non-randomized patients)

Participating Centers	Number of records in group
001 - Istanbul	23
002 - Dresden	17
003 - Magdeburg	0
004 - Coswig	39
005 - Uniklinik Muenster	0
006 - NYC Cornell Medical College	2
007 - LMU Muenchen	15
008 - Hospital General Universitario de Valencia	2
009 - Freiburg	4
010 - Insular Hospital, Gran Canaria, Spain	7
011 - Academic Medical Center Amsterdam	4
012 - Aachen, Germany	0
013 - Hospital Álvaro Cunqueiro, Vigo, Spain	17
014 - Zagreb, University Hospital, Croatia	13
015 - Sotiria Chest Hospital, Athens - Greece	18
016 - Institutul de Pneumoftiziologie Bucharest, Romania	0
017 - Military Medical Academy, Belgrade, Serbia	8
018 - Hospital Universitario de La Ribera	12
019 - Ospedale Policlinico San Martino, Genova, Italy	1
020 - General University Hospital, Prague, Czech Republic	1
021 - HOSPITAL CLÍNIC. UNIVERSITAT DE BARCELONA, Spain	6
022 - Central Military Emergency University Hospital Bucharest	0
023 - Radboud University Medical Centre Nijmegen, The Netherlands	3
024 - ATTIKON UNIVERSITY HOSPITAL (ATHENS, GREECE)	3

Changes to the database

After your feedback concerning data entry, we decided to update the database. Three changes have been made.

In the “Postoperative pulmonary complications” section, we added the field “no chest x-ray”. If a patients shows signs of pleural effusion on day 1, please mark pleural effusion = yes. On day 2 no chest x-ray has been made, therefore you can mark “”no chest x-ray”. On day 3 the pleural effusion is no longer present, please mark pleural effusion=no.

ARDS **according to Berlin definition** * must provide value	○ yes ◉ no
Pulmonary infection **new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions** * must provide value	○ yes ◉ no ○ no chest X-ray
Atelectasis **lung opacification with shift of surrounding tissue/ organ towards the affected area** * must provide value	◉ yes ○ no ○ no chest X-ray
please specify	○ left ○ right ◉ both ○ cannot be differentiated
Cardiopulmonary edema **clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray** * must provide value	○ yes ◉ no ○ no chest X-ray
Pleural effusion **blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray** * must provide value	◉ yes ○ no ○ no chest X-ray
please specify	○ left ◉ right ○ both ○ cannot be differentiated
Pneumothorax **free air in the pleural space on chest X-ray/ ultrasonic imaging** * must provide value	○ yes ◉ no ○ no chest X-ray
pulmonary infiltrates **monolateral/ bilateral infiltrates without other clinical signs** * must provide value	○ yes ◉ no ○ no chest X-ray
Prolonged air leakage **Air leak requiring at least 7 days of postoperative chest tube drainage** * must provide value	○ yes ◉ no

In the “non-mandatory measurements” section, laboratory values should be entered. We changed the order of the field in a logical way (hematology, hemostaseology, clinical chemistry)

Laboratory tests obtained * must provide value	(H) ◉ yes ○ no
Hb	(H) 5.8
Hb, measurement unit	(H) ◉ mmol/l ○ g/dl
Hematocrit	(H) 28 %
WBC	(H) 18.56 GPt/L
Platelets	(H) 267 GPt/L
INR	(H) 1.23 INR
PTT	(H) 29 seconds
Creatinine	(H) 70
Creatinine, measurement unit	(H) ◉ µmol/l ○ mg/dl
BUN	(H) 3.4
BUN, measurement unit	(H) ◉ mmol/l ○ mg/dl
ALT	(H) 0.21
ALT measurement unit	(H) ◉ µmol/s*l ○ U/L
AST	(H) 0.48 U/L
AST measurement unit	(H) ◉ µmol/s*l ○ U/L
Bilirubin	(H) 8.6
Bilirubin, measurement unit	(H) ◉ µmol/l ○ mg/dl
CRP c-reactive protein	(H) 107.3 mg/l
Procalcitonin	(H) 0.4 ng/ml

Several centers asked where to record the “28-day-hospital free-days” value. Initially we intended to calculate this data from the randomization date, the discharge date, as well as the entries in the field “rehospitalisation after discharge”. We will use this procedure as plausibility control, but we decided to add a new field which is called “hospital free days at day 28”. The definition of this value is given next to the entry field.

“defined as the number of days that a patient was not in hospital nor rehabilitation or nursing facility at day 28 after randomization. Hospital readmission is only counted if the patient stays overnight (= 2 days). Patients who die or have longer length of stay than 28 days are assigned zero hospital free days”.

Please note, if your patient dies during the hospital stay/follow up, this value should be ZERO!

Some centers asked, when to record a rehospitalisation after discharge, for example when the patient comes to hospital for outpatient consultation. Rehospitalisation is defined as hospital stay overnight, this means that the patients is physically in the hospital at midnight.

Follow-Up

Please use following Format for Patient-ID: 001001. First 3 digits: site code, last 3 digits patient-ID

Data Access Group: **002 - Dresden**

Editing existing Patient Serial Number **002017**

Event Name: **Follow Up Day 90**

Patient Serial Number	002017
Date of follow up * must provide value	[DD-MM-YYYY]
Lost to follow up? * must provide value	yes no
Rehospitalisation after discharge	yes no Hospital readmission is only counted if the patient stays overnight (= 2 days)
Hospital free days at day 28	defined as the number of days that a patient was not in hospital nor rehabilitation or nursing facility at day 28 after randomization. Hospital readmission is only counted if the patient stays overnight (= 2 days). Patients who die or have longer length of stay than 28 days are assigned zero hospital free days
Alive or dead at day 90 after study inclusion	Alive Death
Form Status	
Complete?	Incomplete
	-- Cancel --

Invitation to Euroanaesthesia 2018

We cordially invite you to participate in the **Steering Committee Meeting of the PROTHOR Trial** that will be held during the European Anaesthesiology Congress in Copenhagen.

Euroanaesthesia THE EUROPEAN ANAESTHESIOLOGY CONGRESS COPENHAGEN 02-04 JUNE 2018

We will report on the status of the trial, and discuss possible sub-studies. If you are interested to run your own sub-study, please write your project draft to Thomas.Kiss@uniklinikum-dresden.de not later than 20 May. This is an unique opportunity get together with other investigators and participate in the largest study on mechanical ventilation during thorax surgery ever. You can bring interested investigators who are not yet participating with you.

We will be pleased to welcome you in **Meeting room 20 on Saturday, 2 June 12:15 - 13:45**

If you have any questions, please contact thomas.kiss@uniklinikum-dresden.de.

Best regards,

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