

PROTHOR Newsletter July 2019 and ESA Steering Committee Meeting Summary

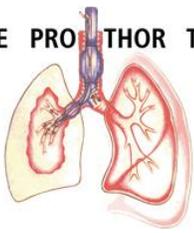
Dresden, July 3, 2019

Dear contributors to the PROTHOR study,

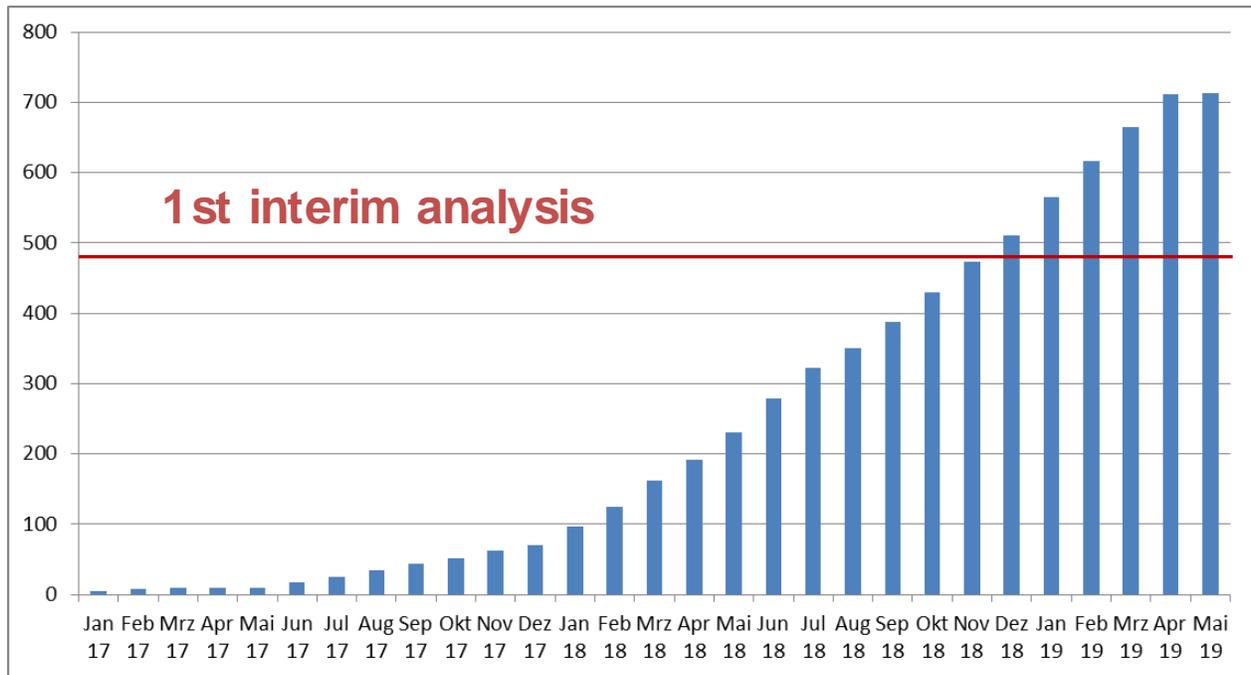
The PROTHOR study steering committee meeting was held at ESA congress in Vienna 4 weeks ago and I want to give you a summary of the main topics. The take home message of the meeting was

- 1. We need more participating centers**
- 2. Already registered centers should recruit more patients**

Professor Daniel Sessler, the Chair of our Data Safety and Monitoring Board (DSMB), mentioned that patient inclusion has to be higher, otherwise the study endurance will be too long and other research groups may publish new results which may compromise the main topic of our study. Therefore we would like to encourage all participating centers to reassess whether patient inclusion may be improved.

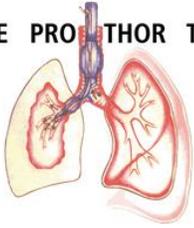


Overview of randomized patients over time (data from May 6 2019)



We have 716 patients successfully included in the study (effective May 6 2019).

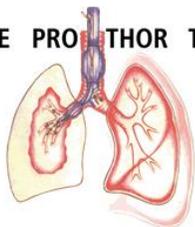
Since January 2019 we are asking for completion of the existing data. In the past months we have been checking the data for the first interim analysis. We have reviewed each center's records for completeness and inconsistencies and sent a detailed Database Review Report, which contains all issues found. We had 14% of missing data at the end of May, therefore we would like to kindly ask you complete the unresolved datasets. The second interim analysis will be performed when reaching 952 patients (40% of the total data). Several centers have completed their missing data just after arriving back home after the ESA congress. We will again go through all datasets and review the records for missing data.



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All registered centers are listed here: <http://prothor.info/doku.php?id=200:CfCenters>

- 001 Istanbul, Turkey
- 002 Dresden, Germany
- 003 Magdeburg, Germany
- 004 Coswig, Germany
- 005 Münster, Germany
- 006 NYC Cornell Medical College, USA
- 007 LMU München, Germany
- 008 Hospital General Universitario de Valencia, Spain
- 009 Freiburg, Germany
- 010 Insular Hospital, Gran Canaria, Spain
- 011 Academic Medical Center Amsterdam, The Netherlands
- 012 Uniklinikum Aachen, Germany
- 013 Hospital Álvaro Cunqueiro, Vigo, Spain
- 014 University Hospital Centre Zagreb, Croatia
- 015 “Sotiria” Chest Hospital, Athens, Greece
- 016 Institutul de Pneumoftiziologie “Marius Nasta” Bucharest, Romania
- 017 Military Medical Academy, Belgrade, Serbia (i)
- 018 Hospital Universitario de La Ribera, Valencia, Spain
- 019 Ospedale Policlinico San Martino, Genova, Italy
- 020 General University Hospital, Prague, Czech Republic (i)
- 021 University Hospital Clínic de Barcelona, Spain
- 022 Central Military Emergency University Hospital Bucharest
- 023 Radboud University Medical Centre Nijmegen, The Netherlands
- 024 Attikon University Hospital, Athens, Greece
- 025 University Medical Centre Ljubljana, Slovenia
- 026 OORR Foggia, University of Foggia, Italy
- 027 HOSPITAL MARIE LANNELONGUE, France
- 028 Merheim Hospital, Cologne, Germany
- 029 University Hospital of Heraklion
- 030 Fudan University, Shanghai Cancer Center, Shanghai, China
- 031 Arcispedale Sant’Anna, Ferrara, Italy
- 032 Clinical Center Nis, Clinic for Anesthesia and Intensive Therapy, Serbia
- 033 Taichung Veterans General Hospital, Taiwan
- 034 AOU G.Martino, Messina, Italy
- 035 Rijnstate Hospital, The Netherlands
- 036 Ankara University Medical Faculty, Turkey
- 037 Ankara Atatürk Chest Diseases And Chest Surgery Training and Research Hospital, Turkey
- 038 Cukurova University Medical Faculty/Adana, Turkey
- 039 Dokuz Eylül University Medical Faculty/Izmir, Turkey
- 040 Adnan Menderes University Medical Faculty/Aydin, Turkey
- 041 Selcuk University Medical Faculty /Konya, Turkey
- 042 Yuksek Ihtisas University/Ankara, Turkey
- 043 University Hospital Brno, Czech Republic
- 044 American Hospital Tirana, Albania
- 045 VU medical center Amsterdam
- 046 Acıbadem Mehmet Ali Aydınlar University, Istanbul, Turkey
- 047 Mersin University Medical Faculty, Dept. of Anesthesiology, Mersin, Turkey

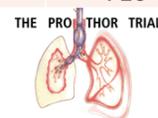


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- 048 Marmara University Medical Faculty, Dept. of Anesthesiology, Istanbul, Turkey
- 049 Istanbul Dr. Siyami Ersek Hospital, Dept. of Anesthesiology, Istanbul, Turkey
- 050 Kocaeli University Medical Faculty, Dept. of Anesthesiology, Kocaeli, Turkey
- 051 Uludağ University Medical Faculty, Dept. of Anesthesiology, Bursa, Turkey
- 052 Istanbul University Cerrahpasa Medical Faculty, Dept. of Anesthesiology, İstanbul, Turkey
- 053 Istanbul Kartal Dr. Lutfi Kirdar hospital, Dept. of Anesthesiology, Ist
- 054 Celal Bayar University Medical Faculty, Dept of Anesthesiology, Manisa, Turkey
- 055 University Hospital Dubrava, Zagreb, Croatia
- 056 University Hospital Bratislava Ruzinov, Slovakia
- 057 “G. PAPANIKOLAOU” General Hospital Thessaloniki Greece
- 058 University Hospitals Bristol NHS Foundation Trust (Bristol Royal Infirmary)
- 059 University Hospital of Dijon - François Mitterrand

Center performance

#	center	number of patients	#	center	number of patients
1	004__coswig	55	19	021__hospital_clni	16
2	009__freiburg	47	20	033__taichung_vete	14
3	030__fudan_univers	45	21	036__ankara_univer	14
4	015__sotiria_chest	44	22	006__nyc_cornell_m	13
5	023__radboud_unive	44	23	011__academic_medi	11
6	024__attikon_unive	43	24	035__rijnstate_hos	10
7	001__istanbul	35	25	010__insular_hospi	7
8	018__hospital_univ	34	26	003__magdeburg	5
9	017__military_medi	31	27	012__aachen_german	5
10	014__zagreb_univer	29	28	045__vu_medical_ce	4
11	031__arcispedale_s	28	29	053__istanbul_kart	3
12	002__dresden	27	30	008__hospital_gene	2
13	013__hospital_lvar	26	31	032__clinical_cent	2
14	025__university_me	26	32	037__ankara_atatur	2
15	026__oorr_foggia_u	26	33	044__american_hosp	2
16	019__ospedale_poli	24	34	055__university_ho	2
17	007__lmu_muenchen	20	35	020__general_unive	1
18	029__university_ho	18	36	034__aou_gmartino	1
				Total	716

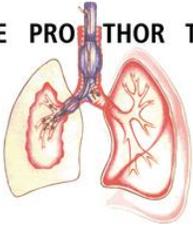


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endorsed by





The PROTHOR Randomized Controlled Trial

We received substudy (requiring study protocol amendment) and secondary analysis proposals (analysis of recorded data not part of the main paper without changes to the study protocol). If you are interested in participation, please contact Thomas Kiss (Thomas.Kiss@uniklinikum-dresden.de)

Substudy:

Non-linear respiratory system mechanics during low versus high positive end-expiratory pressure during thoracic surgery

Proposed by J. Wittenstein, Dresden, Germany

Study protocol amendment already available at the Dresden Ethics Committee

Substudy:

Analysis of inflammation markers from blood samples

Study protocol amendment already available at the Dresden Ethics Committee

Secondary Analysis:

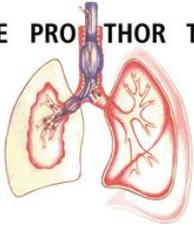
Effects of regional analgesia on post operative pulmonary complications during ventilation with low tidal volume and low PEEP or high PEEP with recruitment manoeuvres.

Proposed by M. Heidegger, Munich, Germany

Secondary Analysis:

The effects of volatile anesthesia on post operative pulmonary complications during ventilation with low tidal volume with Low PEEP or with High PEEP and recruitment manoeuvres.

Proposed by Jo Mourisse, Radboud University, Nijmegen, The Netherlands



I am happy to announce that our PROTHOR study protocol has been published on April 11 2019. It is available online (open access) <https://doi.org/10.1186/s13063-019-3208-8>

All centers that have been registered to the PROTHOR database at the time the manuscript has been sent to the journal have been listed in the appendix. All centers that joined the project later, will be mentioned in our next publication. A list showing all centers contributing to the study can be found here: <http://prothor.info/doku.php?id=200:CfCenters>

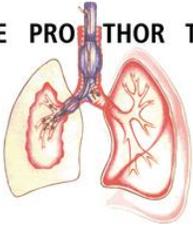
STUDY PROTOCOL

Open Access

Protective ventilation with high versus low positive end-expiratory pressure during one-lung ventilation for thoracic surgery (PROTHOR): study protocol for a randomized controlled trial



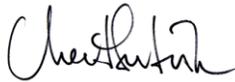
T. Kiss^{1*}, J. Wittenstein^{1†}, C. Becker¹, K. Birr¹, G. Cinnella², E. Cohen³, M. R. El Tahan⁴, L. F. Falcão⁵, C. Gregoretti⁶, M. Granell⁷, T. Hachenberg⁸, M. W. Hollmann⁹, R. Jankovic¹⁰, W. Karzai¹¹, J. Krassler¹², T. Loop¹³, M. J. Licker¹⁴, N. Marczin^{15,16,17}, G. H. Mills¹⁸, M. T. Murrell¹⁹, V. Neskovic²⁰, Z. Nisnevitch-Savarese²¹, P. Pelosi^{22,23}, R. Rossaint²⁴, M. J. Schultz^{25,26}, A. Serpa Neto²⁷, P. Severgnini²⁸, L. Szegedi²⁹, T. Vegh^{30,31}, G. Voyagis^{32,33}, J. Zhong^{34,35}, M. Gama de Abreu¹, M. Senturk²⁶, for the PROTHOR investigators and the Research Workgroup PROtective Ventilation Network (PROVEnet) of the European Society of Anaesthesiology (ESA)



The PROTHOR Randomized Controlled Trial

Thank you so much for your effort and congratulations to all contributors! If you have any questions, please contact me (thomas.kiss@uniklinikum-dresden.de).

Best regards,



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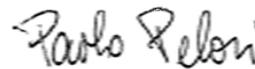
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