

ImmunoSep TRIAL

3rd NEWSLETTER

Dear Investigators,

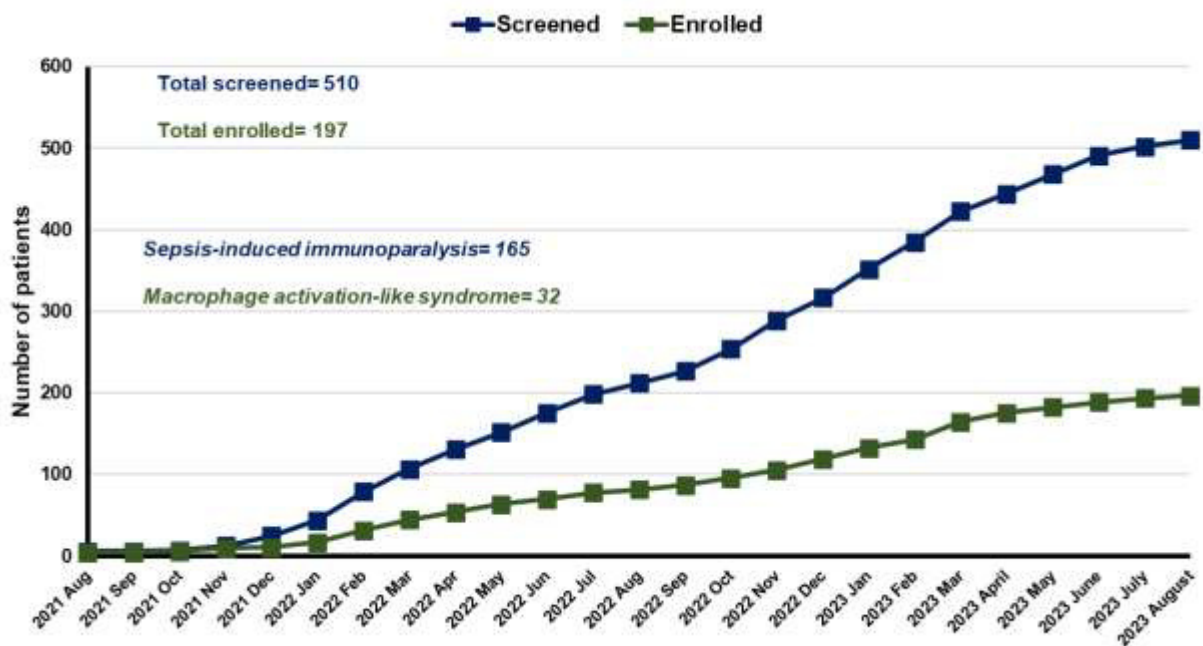
We send you our 3rd Newsletter to keep you updated with the progress of the ImmunoSep trial

As of 1st September 2023:

- 33 sites activated
- 510 patients screened
- 197 patients randomized

Our final Goal: 280 patients randomized by the end of 2023

ImmunoSep MONTHLY PROGRESS



MALS: macrophage activation-like syndrome

Update from the interim safety report

Data Safety Monitoring Board (DSMB) meeting was held in July 2023

Members of the DSMB:

Prof. D. Annane (Paris, France), Prof. A. Artigas (Barcelona, Spain),
Prof. A. Linder (Lund, Sweden)

Analysis of blind data on the first 140 enrolled patients

Outcome: NO safety concern

ImmunoSep is presented in BIG meetings of Critical Care in 2023

- ISICEM Brussels, March 2023
- ECCMID Copenhagen, April 2023
- Clinical trialists Workshop Washington, June 2023
- Sepsis Update Weimar, September 2023
- World Sepsis Day events Paris-Berlin, September 2023

TOGETHER we generate WORLD AWARENESS of SEPSIS IMMUNE CLASSIFICATION

TOGETHER we make reality what the others speak about:

PAVE THE WAY OF PRECISION IMMUNOTHERAPY IN SEPSIS

WHAT REMAINS TO BE DONE?

- 83 patients still to be enrolled
- Let us do our BEST and the marathon ends



Congratulations to Top Contributors

Centre	# Screened subjects	# Enrolment Subjects
Intensive Care Unit, "Ippokrateion" Thessaloniki General Hospital (PI: Eleni Mouloudi, MD, PhD)	125	58
Intensive Care Unit, "AHEPA" Thessaloniki University General Hospital (PI: Eleni Gkeka, MD, PhD)	68	22
4th Department of Internal Medicine, ATTIKON University Hospital, Athens (PI: Prof. Antonios Papadopoulos, MD, PhD)	55	17
Multipurpose Intensive Care Unit, SOTIRIA General Hospital of Chest Diseases of Athens, Athens (PI: Maria Daganou, MD, PhD)	28	16
Intensive Care Unit, "Aghios Dimitrios" Thessaloniki General Hospital (PI: Glykeria Vlachogianni, MD, PhD)	19	4
Intensive Care Unit, Amsterdam University Medical Center (PI: Alexander Vlaar, MD, PhD)	18	4

Useful tips to remember

INCLUSION CRITERIA

- Sepsis is defined by Sepsis-3 criteria
- Type of infections: BSI, all lung infections*
- Both COVID-19 and non-COVID-19 patients

*community-acquired pneumonia, hospital-acquired pneumonia, ventilator-associated pneumonia

Useful tips to remember

- Previous 10-day dexamethasone course: DO NOT exclude the patient
- Previous treatment with Tocilizumab, Anakinra and Baricitinib: DO NOT exclude the patient

Please continue to update the eCRF daily AND REMEMBER

- <https://www.sepsisonline.org>
- SOFA is THE primary endpoint!
- Report ALL severe and non-severe treatment-emergent adverse events



The ImmunoSep project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 847422.