

DONARE Study Final Results – Randomized Research on in-situ adsorption of proinflammatory mediators in controlled DCD donors

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DONARE Study Working Group

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Background

Donation after cardiac death (DCD) can be an important source for expanding the numbers of organs suitable for transplantation. Italian peculiarities (20minutes no-touch-period) in controlled DCD (cDCD) raise concern over organ ischemic damage, even performing Normothermic Regional Perfusion (NRP), highly recommended in all potential cDCD donors. DONARE study was designed as a randomized trial in 2019 to evaluate whether the insertion of a system capable of adsorbing inflammatory mediators during NRP leads to a reduction in cellular oxidative damage potentiality, assessed as a decrease in the levels of proinflammatory substances.

This report describes the general final results.

Methods

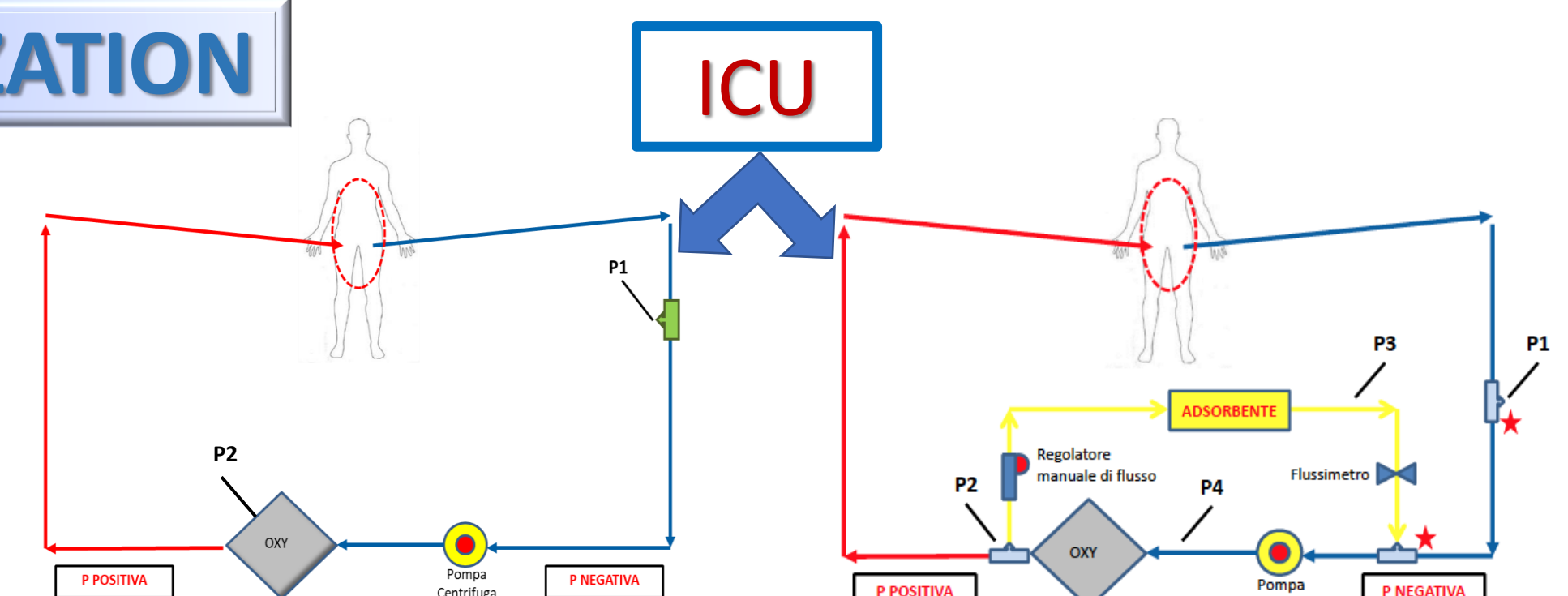
The study protocol was defined by the DCD national working group and proposed to all the Italian DCD donation centers. The coordinating center (Italian National Transplant Center, CNT) has monitored the evolving cDCD activity

- ✓ To describe the trend of **ischemic-reperfusion and inflammatory (cytokines) biomarkers** during **NRP**
- ✓ To test the **potential benefit of an adsorbent filter (CytoSorb)** included in parallel the ECMO/NRP circuit (**In situ Organ Perfusion Apheresis**)

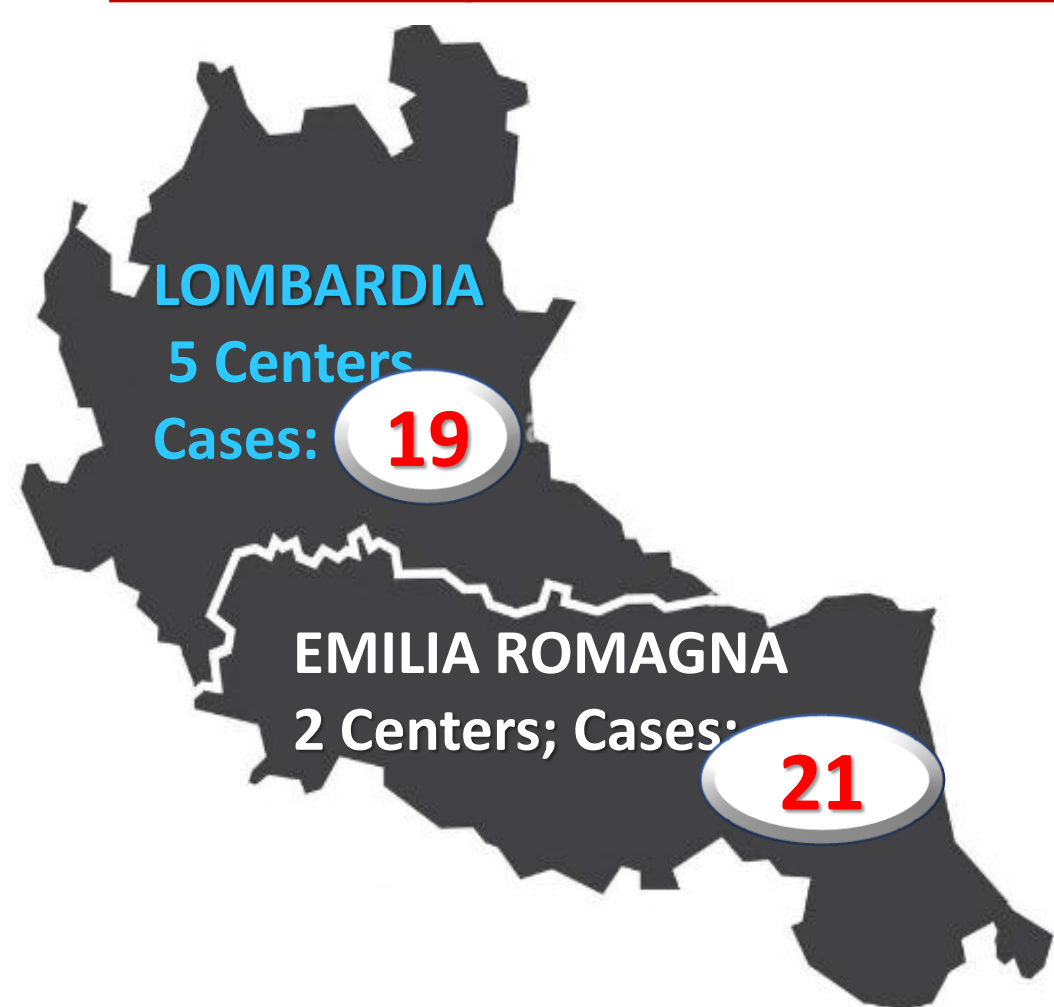
Results

CENTRALIZED RANDOMIZATION

- **40 cDCD:** Randomization 1:1 in treatment with the adsorbent filter (CytoSorb) and Control group



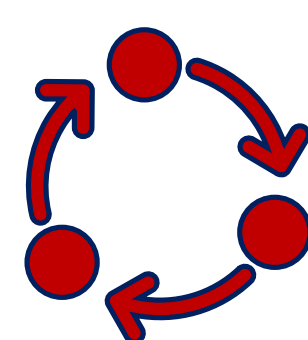
- **7 Transplant Centers**



DONOR AGE (years)

Mean	SD	Min	Max	Median
64,5	10,5	41	81	66

- **38/40 (98%) donors utilized**
- **No adverse effects related to the Study**



NRP flows decreasing from t_0 - t_{end} No influence on CytoSorb Flow
IL-6, IL-8, IL-10, TNFa quantified



Abnormally high cytokines levels, increasing over time, with lower tend values in CytoSorb Group

Conclusions

The final evaluation for the DONARE study shows the safety and the feasibility of Apheresis integration in NRP for inflammatory mediator modulations in cDCD donors.