

controlled clinical trials are hardly feasible, among others because of the substantial administrative and financial burden on the required patient recruitment. In addition, rare acute diseases are usually outside the interest of research-based pharmaceutical industry, because, unlike rare chronic illnesses, medication is limited in time and sales revenue is not guaranteed. In contrast, registry observations allow an almost complete picture of the target population and insight into potential treatment options.

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International registry on the use of the CytoSorb®-Adsorber in ICU patients (NCT02312024)

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Introduction: Clinical registries are valuable tools for assessing long term benefits of medical applications. The efficacy of treatment methods and medical devices can be evaluated and compared. In addition, registries are supportive of the transfer new technologies into clinical routine.

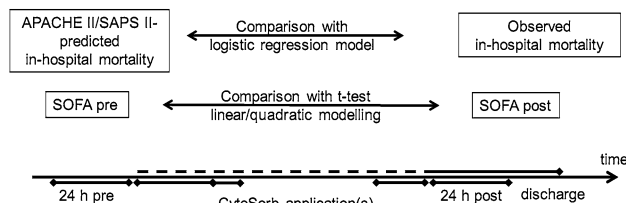
Objectives: The aim of this registry is to record the use of CytoSorb® under real life conditions in as many cases as possible (preferably all or, at least, in a representative sample). All CytoSorb® applications in different clinical settings and in all patients who are treated with this technology are planned to be included (Study website: <http://www.cytosorb-registry.org/>).

Methods: The objectives of the registry are collection of real-life data on a broad scale, their centralized, structured and comprehensive documentation, and a controlled data exchange. The gathered information will be used to augment the knowledge on the clinical efficacy of the technology, to optimize the quality of its therapeutic application, and to identify and promptly handle possible complications related to the use of CytoSorb®. The registry will record all relevant information in the course of product use, e.g. diagnosis, comorbidities, course of the condition, treatment, concomitant medication and clinical laboratory parameters. The registry will inform physicians of different medical specialties about the range of possible applications of CytoSorb® and invite them to contribute their own experiences to the registry. This is done by giving them access to their own data and to the results of periodic analyses (for contributing participants), and via publications of the results (for participants and external interested parties)

Results: The CytoSorb® registry will provide the data base for justified and optimized decisions. An active form of data collection where data is prospectively collected by qualified staff is particularly suited for this purpose. Registry data might help closing knowledge gaps and open practical issues. Due to the patient group's heterogeneity, the registry can identify sub-groups, assess their risk–benefit-profile and examine their safety profile. Registry data are absolutely essential for assessing a therapy's significance within the healthcare landscape.

Institutions that contribute data to the registry benefit in several ways: They will obtain a continuous retrospective feedback of their own results, their data will be periodically compared with data from other participating sites, and they will get access to regularly published analyses of the results of all participants. On the basis of these data, they can establish a quality monitoring and optimize their use of CytoSorb®.

Conclusions: The planned endpoints allow for a comprehensive description of CytoSorb® efficacy in terms of several indication-relevant aspects. Together with the monitoring of application safety, these data build the basis for establishing benchmarks that promote a higher treatment quality.



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Case report of 1 Patient with multiorgan failure due to severe SIRS in cardiac failure treated additional with Cytosorbents haemadsorption as adjunctive therapy

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Introduction: In several studies and in vitro data is demonstrated that the additional treatment with an extracorporeal cytokine adsorption filter (CytoSorb®) may be helpful not only in patients with septic multiple organ failure but also e.g. in severe pancreatitis or other critical diseases due to an excess of cytokines (1). The effect is based on biocompatible, highly porous polymer beads able to capture and adsorb cytokines and other middle molecules (1, 2, 5, 6, 9, 11, 12). CytoSorb® therapy has meanwhile been used in over 200 hospitals worldwide in more than 5500 patients and is well tolerated and safe.

Methods: We treated one patient with severe SIRS and multiorgan failure in cardiogenic shock due to refractory cardiac arrhythmia. Hospital admission of our patient took place after she collapsed several times at home. Glasgow Coma scale was 11, heartrate was ~20 bpm, hypothermia was measured with 30 °C, metabolic acidosis with pH 7.2, no blood pressure measurable. Immediately resuscitation followed and after that, the patient developed severe SIRS and multiorgan failure in cardiogenic shock due to refractory cardiac arrhythmia. Patients history results in peripheral arterial obstructive disease, arterial hypertension and former minor stroke.

Initial ultrasound of the heart function shows diffuse hypokinesia and an ejection fraction at about 45 % with a heartrate by 36 bpm. After 24-h conventional treatment (differentiated catecholamine therapy with combined norepinephrine and adrenaline, ultrasound guided volume therapy, lung-protective ventilation, administering temporary cardiac pacemaker), CytoSorb® therapy and CRRT was initiated because of no decline in catecholamine demand associated with a persistent renal failure. Ultrasound control showed diffuse dysfunction and hypokinesia with an ejection fraction at about 50 %. Chest X-ray at admission shows Fig. 4. Laboratory and electrocardiography at admission showed neither myocardial infarction nor infectious items but high elevated liver enzymes and creatinine (Table 1).

Before treatment, during treatment and after treatment with CytoSorb® we calculated or collected SAPS II-Score, SOFA-Score, mean arterial pressure, requirement of norepinephrine, and blood lactate level. Furthermore we calculated the demand of norepinephrine (µg/h vs. mm Hg MAP) during therapy. The