S.A.I.L.I.N.G.

Studies on Adsorption International Learning Initiative Global

1) Research and Researcher's Information

Research Topic	The use of sorption technologies in patients receiving program hemodialysis with inflammatory syndrome		
Key Words	Program dialysis Sorption Complications of program dialysis	Specialty	Nephrology Blood Purification Therapy
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Research Start and Completion Time	September 2024 August 2025		

2) Research Abstract

Research Topic	Use of sorption technologies in patients undergoing maintenance hemodialysis with inflammatory syndrome and clinical manifestations of uremia
Study Aim	To evaluate the effect of hemosorption with the Jafron HA130 cartridge combined with hemodialysis on inflammatory markers and clinical symptoms of uremic intoxication
Study Design	This study will involve 30 hemodialysis patients selected based on examination results showing elevated C-reactive protein (CRP) and/or interleukin-6 (IL-6) levels. Participants will undergo hemoadsorption with the Jafron HA130 cartridge performed concurrently with hemodialysis: three times per week during the first month, twice per week during the second month, and once per week during the third month.The following parameters will be assessed: inflammatory markers (CRP, IL-1, IL-6, IL-8, β2-microglobulin, free light chains of immunoglobulins), parathyroid hormone (PTH), standard biochemical blood tests (creatinine, urea, calcium, phosphorus, albumin, iron metabolism), and complete blood count. Analyses will be performed at baseline (before inclusion) and monthly thereafter.The total study duration will be three months.
Total Patient Number	60 patients
Selection of the Patients	1. Adequate dialysis defined by a KT/V index ≥ 1.4 2. No active inflammatory process or infection 3. Age ≥ 18 years 4. Receiving standard hemodialysis regimen three times weekly, at least 4 hours per session 5. Elevated interleukin-6 (IL-6) and/or C-reactive protein (CRP) levels above reference values
	Exclusive Criteria: 1. Current use of steroids or immunosuppressive therapy 2. History of kidney transplantation 3. Diagnosis of cancer 4. Pregnancy
	Intervention Group

Treatment Plan	Dialysis patients will undergo a combined procedure (hemodialysis and hemosorption) using the Jafron HA130 cartridge three times a week in the first month, twice a week in the next month, once a week in the third month.
	Control Group Patients on standard dialysis procedure (30 patients)
Endpoints	Primary Endpoints The effectiveness of combined procedures (hemodialysis + hemosorption) compared with standard hemodialysis in reducing the level of the IL-6
	Secondary Endpoints Change from baseline in serum Il-1, IL-8, IL-10, CRP, beta2-microglobulin, free light chains, PTH, serum iron, ferritin, TS, phosphorus, calcium, BUN, creatinine, Hb. Change from baseline in Hospital Anxiety and Depression Scale Score Change from baseline in pruritus (Visual Analogue Scale)
	Safety Index Assess safety based on the number of serious adverse events and adverse events
Statistics Method	The assessment will be carried out using standard statistical methods
Expected Results	Reduced levels of inflammatory markers, middle molecules and associated uremic manifestations
The Importance of Study	Improved treatment results
Study Duration	1 year