

## **Study Protocol**

**Official title of the study:** Recovery Time and Affecting Factors

**NCT number:** NCT04274556

**Date of document:** May 11, 2020

**Objective:** The aim in this study was to investigate the effects of biochemical parameters and intradialytic symptoms on post-dialysis recovery time in patients undergoing chronic hemodialysis (HD).

**Design:** Descriptive and cross-sectional study

**Methods:** The study was conducted in accordance with the Declaration of Helsinki. Permission was obtained from the local ethics committee (Meeting Date: 2019/07, Decision No: 03) and the relevant institutions in addition to written consent from the subjects.

This study was conducted in a private dialysis center between June and August 2019. The inclusion criteria were being on HD for 4 hours a day on 3 days per week for at least 6 months, aged 18 years or older with no communication problem and volunteering to participate in the study. Patients who did not volunteer to participate were excluded.

## **Statistical Analysis Plan**

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### **Outcome measures**

**Post-dialysis Recovery Time:** Before the hemodialysis session, the patients were asked by the investigators how long it took them to recover from a dialysis session, taking the last treatment month into account.

**Intradialytic Hypotension:** It is defined in the European Best Practice Guideline (EBPG) as a decrease of 20 mmHg or more in the systolic blood pressure or 10 mmHg or more in the mean arterial blood pressure together with symptoms requiring nursing intervention.

**Dialysis Symptom Index:** It was identified with Dialysis Symptom Index (DSI). DSI consists of 30 items. We queried the subjects regarding symptoms in the last 7 days. The effect was evaluated with a Likert type scale from 0 to 4, representing "not at all" to "significantly". The total score of the DSI ranges from 0 to 150. A score of zero reflects no symptoms while increasing total scores reflect increasing effects of the symptoms.

### **Statistical analysis**

The Statistical Package for Social Sciences (SPSS Inc., Chicago, IL., USA) 22.0 software program was used for the statistical analysis of the data obtained from the study. The Shapiro-Wilk Test was used to determine data normality. Continuous numeric variables were presented as mean $\pm$ standard deviation (SD), median, and interquartile range (IQR), while categorical variables were presented as numbers (n) and percentages (%). Comparisons of the data without a normal distribution were made by using the 'Mann-Whitney U Test' and 'Chi-square Test' while the comparisons of the data with a normal distribution were made with 'Student's *t* Test'. The 'One Way ANOVA Test' was used for three-group analysis in case of normally distributed variables. Homogeneity of the variables was analyzed with the Levene Test. In case of any difference in the multi-group analysis, a post-hoc intergroup analysis was done with the Tukey Test. For three-group analysis, the 'Kruskal-Wallis Test' and 'Chi-square Test' were used for abnormally distributed variables. Post-hoc intergroup analysis was done with the 'Bonferroni-Corrected Mann-Whitney U Test'. The independent predictors among factors affecting the post-dialysis recovery time were evaluated with logistic regression analysis by using the possible factors that had been predefined in the previous analysis. A P value  $<0.05$  was accepted as statistically significant.

## Results

Title:	Post-dialysis Recovery Time		
► Description:	Before the hemodialysis session, the patients were asked by the invest...		
Time Frame:	Up to 7 days		
▼ Outcome Measure Data			
► Analysis Population Description			
Arm/Group Title	Post-dialysis Recovery Group		
► Arm/Group Description:	Before the hemodialysis session, th...		
Overall Number of Participants Analyzed	86		
Mean (Standard Deviation)	278.02 (209.94)		
Unit of Measure: minutes			

Title:	Number of Participants With Intradialytic Hypotension		
▶ Description:	It is defined in the European Best Practice Guideline (EBPG) as a decr...		
Time Frame:	Up to 7 days		
▼ Outcome Measure Data			
▶ Analysis Population Description			
Arm/Group Title		Post-dialysis Recovery Group	
▶ Arm/Group Description:		Before the hemodialysis session, th...	
Overall Number of Participants Analyzed		86	
Measure Type: Count of Participants			
Unit of Measure: participants			
Row Title			
Existing of intradialytic symptoms		42	48.84%
Absent of intradialytic symptoms		44	51.16%

Title:	Rate of Dialysis Symptoms		
► Description:	It was identified with Dialysis Symptom Index (DSI). DSI consists of 3... If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.		
Time Frame:	Up to 7 days		
▼ Outcome Measure Data			
► Analysis Population Description			
Arm/Group Title		Post-dialysis Recovery Group	
► Arm/Group Description:		Before the hemodialysis session, th...	
Overall Number of Participants Analyzed		86	
Mean (Standard Deviation)		19.10 (14.29)	
Unit of Measure: score on a scale			