

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±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 decre...
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
Absent of intradialytic symptoms	44
	48.84%
	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	