Mobilization of Fluid and Fluid Flows in Hemodialysis

21st March 2024

Statistical Analysis Plan

1. Statistics

1.1. Population to be analyzed

- In the protocol 15 patients are included in each group, with the ambition to reach totally 30 evaluable patients (per protocol), defined as patients completing the study. If a patient is excluded during or before the study, the patient will be replaced. Patients excluded from the study after inclusion will be accounted for as dropouts.
- The study will be performed in Norrköping.

1.2. Statistical analysis

1.2.1. Statistical method

- A two-sided test of significance will be used.
- After the last patient has been included an evaluation will be made if results are distributed according to the norm. If so, parametrical statistical methods will be used i.e., T-test.
- If these are not distributed according to the norm the Wilcoxon test will be used.
- Recruitment of fluid is the primary variable.

If the study is dissected, it contains two groups:

A. Patients with a fluid withdrawal of less than 500 ml
B. Patients with a fluid withdrawal of more than 2000 ml

Statistical processing of the primary outcome

In the first analysis total recruitment of fluid from the tissues will be evaluated.

Total recruitment and AUC (Area under the curve) for recruited fluid, i.e., fluid removal and hemoglobin changes. Moreover, the inverted half-life for recruitment will be determined.

In the secondary analysis, the proportions of the fluid recruitments via lymph or via capillary/venular walls will be performed

Methods: One way test, T-test or Wilcoxon.

Secondary outcome

Weight, blood pressure and changes in bio-impedance variables will be correlated to withdrawal of fluid.

1.2.2. Drop outs

Drop outs, i.e., included patients who do not complete the study, will be accounted for. However, to make up for the drop outs additional patients will be recruited.

1.3. Adjustment of sicnificans and confidens

The primary outcome measurement is the fluid recruitment (Ultra filtrate and hemoglobin changes) from the tissues; no correction for multiple comparisons has to be performed. All other measurements are secondary: thus no corrections for multiple comparisons will be done for these either. However, the problem will be considered in the interpretation of the results. Especially if analysis results are weak positive.

1.4. Calculation of dimension

- The sample calculation for the outcome is based on a comparison between two groups, i.e.,ultrafiltration <500 ml vs ultrafiltration >2000 ml.
- **Statistics:** With a desired P-value of <0.05 and a Power of 80 % with a difference (fluid recruitment) of 25% and a standard deviation of 20% and a two-sided test, 11 individuals in each group are needed. At least 15 patients in each group fulfilling the study will be recruited.