EUDIAL – An Official ERA-EDTA Working Group
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HOW TO SET THE STAGE FOR A FULL-FLEDGED CLINICAL TRIAL TESTING "INCREMENTAL HAEMODIALYSIS"

PROJECT DESCRIPTION

The optimal regimen for patients starting haemodialysis (HD) is not known. It is plausible that the routine practice of a thrice-weekly HD (3HD/wk) regimen in incident patients with substantial residual kidney function (RKF) may be harmful, contributing to accelerated loss of RKF. At the present time no randomized controlled trial (RCT) testing "incremental HD" has yet been published [1].
The EUDIAL Working Group is starting an RCT in incident HD patients, whose name is "REAL LIFE", by using the acronym of its whole definition: RandomizEd clinicAL triaL on the effIcacy and saFety of incremental haEmodialysis.
REAL LIFE is a pragmatic, prospective, multicentre, open label RCT, investigator-initiated, comparing the intervention arm (incremental HD) with the control arm (standard 3HD/wk). Incident patients will be randomized to one of the two treatment groups in equal proportion. To ensure adequate concealment of allocation, the randomization will be performed using a central computer.
Patients will be recruited from dialysis centres in Europe. Primary outcome is preservation of RKF assessed as time to anuria (urine output ≤ 100 mL/day). Secondary outcomes are the slope of KRU decline over time, all-cause mortality, significant events, including vascular access failure and associated interventions, cardiovascular events, and hospital admissions. The follow-up time will be 24 months. The statistical analysis will be done by means of the intention-to-treat approach. The prescription of incremental HD will be based on the variable target model (VTM) [2]. VTM allows to start and keep patients on once-weekly HD schedule if residual renal urea clearance (KRU) is between 3.0 and 4.5 mL/min/35 L. Once-weekly HD should be possible until KRU falls below 2.5 – 3.0 mL/min/35 L, i.e., a glomerular filtration rate (GFR) ≈ 4 mL/min/35 L. All patients allocated to the intervention arm will keep on the twice-weekly schedule until KRU falls below 1.5 mL/min/35 L; afterwards, the 3HD/wk schedule must be started. The intervention arm patients (once- and twice-weekly HD schedule) should receive an equilibrated Kt/V (eKt/V) of about 1.2 per session.
The assessment of the key kinetic parameters will be done by using SPEEDY [21], a spreadsheet prescription tool. Click here to learn.

1. Basile C, Casino FG on behalf of the EUDIAL Working Group of ERA- EDTA (2019) Incremental haemodialysis and residual kidney function: more and more observations but no trials. Nephrol Dial Transplant 34: 1806 – 1811
2. Casino FG, Basile C (2017) The variable target model: a paradigm shift in the incremental haemodialysis prescription. Nephrol Dial Transplant 32: 182 – 190
3. Casino FG, Basile C (2018) A user-friendly tool for incremental haemodialysis prescription. Nephrol Dial Transplant 33: 1046 – 1053

DETAILS OF THE FELLOWSHIP

1. **Duration of the fellowship**: 12 months
2. **Location of the hosting centre**:

Nephrology, Dialysis and Transplantation Unit
"Aldo Moro" University of Bari

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3. **Principal Investigators of the project**:
Carlo Basile, MD
Francesco G. Casino, MD
Name of the Fellow's Supervisor
Loreto Gesualdo, Prof.

4. **Start of the fellowship**: January 2021

5. **Qualifications and/or expertise required:**
1. expertise in biostatistics and epidemiology;
2. previous experiences in the conduction and monitoring of randomized controlled trials.

GRANTED AMOUNT

EUR 35,000