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Clinical significance of Malnutrition-Inflammation-Atherosclerosis Syndrome in the patients on maintenance hemodialysis

Submission date
06/08/2007

Recruitment status
No longer recruiting

Registration date
06/09/2007

Overall study status
Completed

Last Edited
22/05/2019

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1/2005

Study information

Scientific Title

Clinical significance of Malnutrition-Inflammation-Atherosclerosis Syndrome in the patients on maintenance hemodialysis

Study objectives
Application of atorvastatin or Helixone® dialysis membrane or online hemodiafiltration would have beneficial effect on the morbidity and mortality of the patients with Malnutrition-Inflammation-Atherosclerosis (MIA) Syndrome on the maintenance hemodialysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Medical School of the University of Rijeka in June 2005.

Primary study design
Interventional

Study design
Single-center, randomised controlled trial.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End-stage renal disease treated with hemodialysis.

Interventions
Participants were randomised into 4 groups:
1. Current dialysis with atorvastatin (10 mg orally per day during the whole follow-up periode [24 months])
2. Dialysis using the Helixone® membrane
3. Online hemodiafiltration
4. Control group: current dialysis treatment only

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Patient survival with or without MIA syndrome at 2 years
2. Survival of patient with MIA syndrome according to randomisation/intervention at 2 years

Key secondary outcome(s)
1. Determinantion of independent predictors of mortality in MIA syndrome patients at 2 years
2. Influence of intervention on laboratory parameters of MIA syndrome at 2 years
3. Safety assessement of atorvastatin application, checked after 1, 3, 6, 12 and 24 months according to known precautions for statin use
4. Hospitalisations rate and frequency of patients with or without MIA syndrome at 2 years

Completion date
01/07/2007

Eligibility

Key inclusion criteria
End-stage renal diasese on maintenance hemodialysis lasting at least 3 months.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
168

Key exclusion criteria
1. Previously transplanted
2. Previously treated with peritoneal dialysis
3. History of active infection in the last 3 months

Date of first enrolment
01/06/2005

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Croatia

Study participating centre
Department of Nephrology and Dialysis
Rijeka
Croatia
51000

Sponsor information

Organisation
Ministry of Science, Education and Sport of the Republic of Croatia

ROR
https://ror.org/0507etz14

Funder(s)

Funder type
Government

Funder Name
Croatian Ministry of Science, Education and Sport (project number 0062015)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2010	22/05/2019	Yes	No