

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

Submission date 06/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/05/2019	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sanjin Racki

Contact details
Department of Nephrology and Dialysis
T. Strizica 3
Rijeka
Croatia
51000
-
sanjin.racki@ri.t-com.hr

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

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.

Study design

Single-center, randomised controlled trial.

Primary study design

Interventional

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. Determination 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 assessment 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 disease 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