

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

**Submission date**  
06/08/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
06/09/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
22/05/2019

**Condition category**  
Urological and Genital Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/06/2005

**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

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

208

**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

### Sponsor details

Trg hrvatskih velikana 6

Zagreb

Croatia

10000

### Sponsor type

Government

### 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

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Results article</a>	results	01/06/2010	22/05/2019	Yes	No