HD-BACT: Subclinical bacteaemia and mortality among haemodialysis patients

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Aim
To investigate the influence of circulating bacterial DNA on
- mortality
- morbidity
- levels of inflammatory markers
among a group of haemodialysis (HD) patients.

Background
- Mortality rate among HD patients is > 20%
- Cardiovascular disease (CVD) is the major course of mortality
- There is a close relationship between inflammation and development of CVD
- 30-60% of HD patients have constantly elevated inflammation markers
- Various factors in the uremic milieu can cause and sustain this inflammation
- Infection may be an important inflammatory factor as well
- Small studies have shown that approximately 20% of a population of HD patients without any sign of clinical infection has circulating fragments of bacterial DNA in the blood stream - these patients do also have elevated hsCRP

Hypothesis
Chronic inflammation in HD patients may be caused by subclinical infection expressed by circulating bacterial DNA in the blood stream causing higher mortality and morbidity

Methods
Study population:
Haemodialysis patients treated in five different haemodialysis facilities
- Aalborg
- Skejby
- Hjørring
- Randers
- Horsens

Patients on chronic haemodialysis above 18 years of age and capable of understanding informed consent are eligible for inclusion.

Procedure:
- Interview with baseline information
- Physical examination
- Blood sample drawn from peripheral vein and from haemodialysis access
- Nasal wipe
- Dialysate samples
- 100 HD patients will be re-examined after one week repeating blood sampling

Blood samples:
- Bacterial DNA - detected by using broad range 16S rDNA PCR.
- Blood cultures
- Inflammation markers: A number of markers from different areas of the inflammatory response are analyzed
- Baseline parameters: Electrolytes, lipids, hemoglobin, creatinine, urea

Primary end point:
- all cause mortality

Secondary end points:
- bacteraemia
- cardiovascular death
- cardiovascular events
- hospital admissions

Status
Study population: 419 patients
80 patients excluded:
- 60 did not meet inclusion criteria
- 20 refused to participate
339 accepted inclusion
2 patients died waiting for inclusion program
337 patients included December 6th 2010 until March 29th 2011