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 inflamma-
tion 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 frag-
ments 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 bac-
terial DNA in the blood stream causing higher mor-
tality 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, hemo-
globin, 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 until March 26th, 2011.