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Effects of Marine n-3 Fatty Acids on Heart Rate Variability and Arrhythmias in Patients Receiving Chronic Dialysis (Renal Rhythm Study II) – Rationale and Design

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Introduction

End Stage Renal Disease (ESRD) patients have an extremely high mortality. Fifty percent of all deaths are cardiovascular related and many due to cardiac arrhythmias.

A high prevalence of various arrhythmias are reported in dialysis patients. Atrial fibrillation (AF) is the most common arrhythmia and often asymptomatic, but can be symptomatic especially during the dialysis treatment. Furthermore, the risk of stroke increases dramatically and the mortality doubles

Autonomic cardiac dysfunction is often seen in patients with ESRD, and this is expressed by attenuated Heart Rate Variability (HRV) which is a measure of the variation in the time interval between heartbeats. Attenuated 24 hours HRV is associated with an increased risk of sudden cardiac death in the general population and among ESRD patients.

Marine n-3 polyunsaturated fatty acids (PUFAs) have been shown to increase HRV and reduce the risk of various arrhythmias. This effect has only been sparsely investigated in the high risk patients with ESRD who has a low intake of n-3 PUFAs.

Hypothesis

n-3 PUFA supplementation increases 24 hours HRV in chronic dialysis patients.

n-3 PUFA supplementation reduces the level of supraventricular tachycardia (SVTs), premature atrial complexes (PACs) and premature ventricular complexes (PVCs) in chronic dialysis patients.

Aims

The purpose of this study is to investigate the effects of n-3 PUFA supplementation on HRV and arrhythmias in patients with ESRD.

Primary endpoint

- 24 hours HRV – SDNN (standard deviation of NN intervals)

Secondary endpoints

- Other HRV indices
- AF and SVTs
- Number of PACs
- Number of PVCs and Low classification

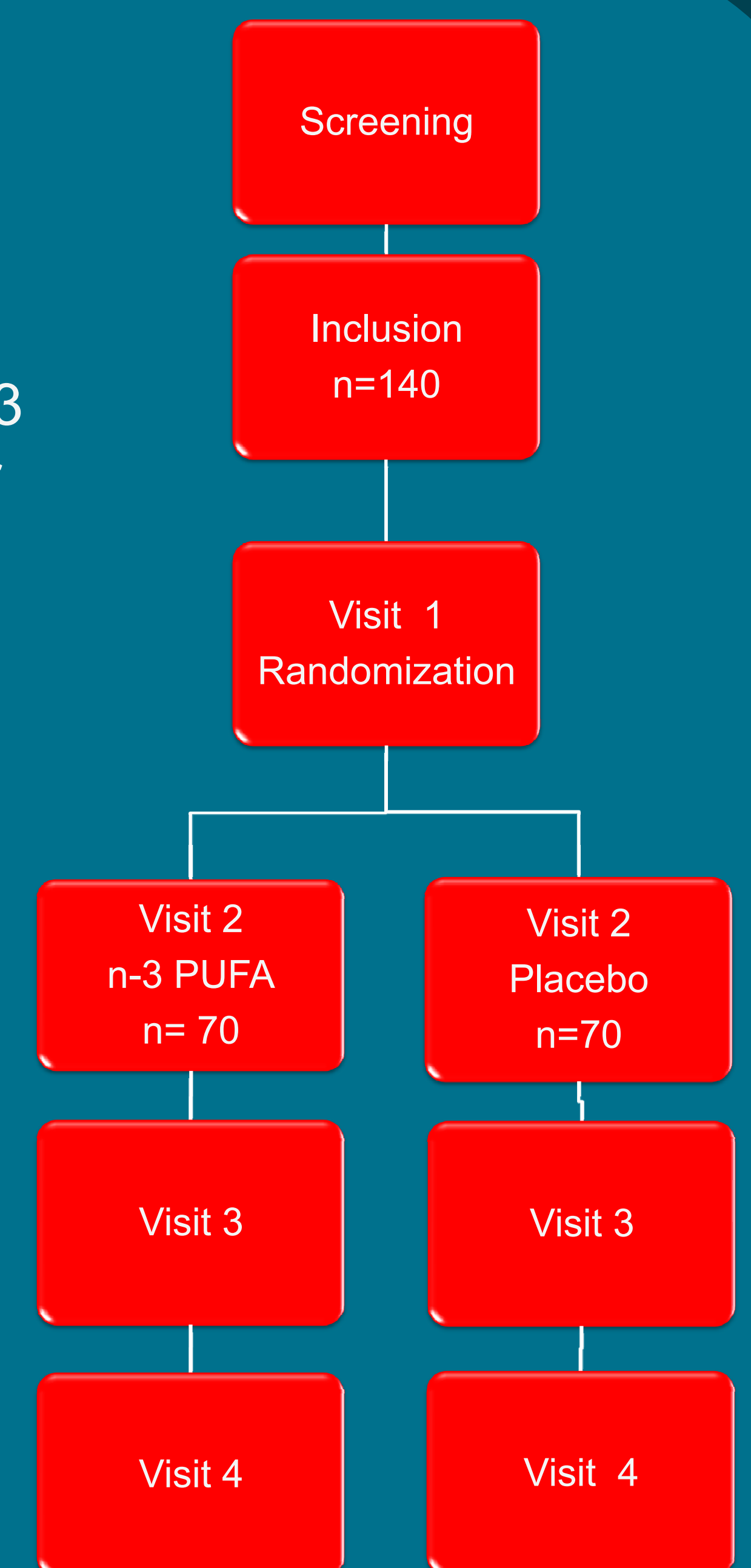
Design

Randomized placebo controlled trial.

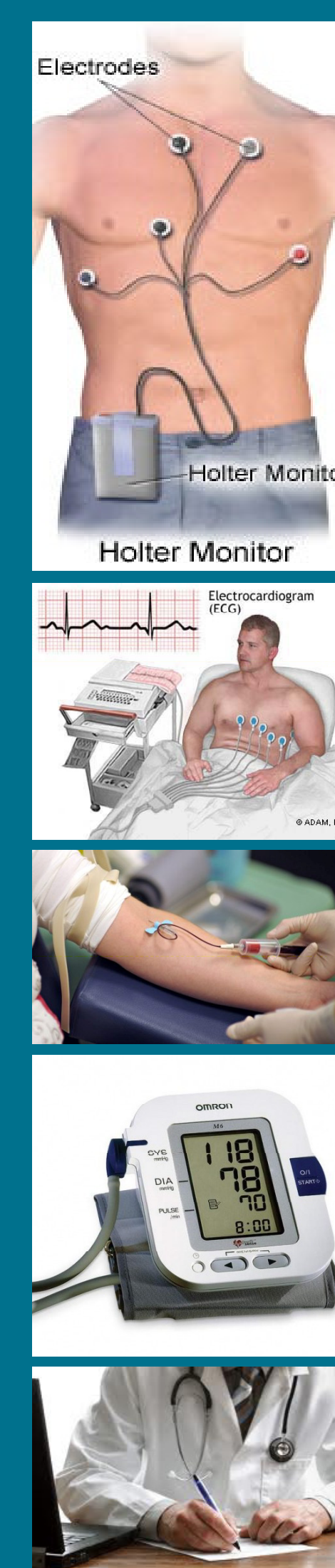
Patients are allocated to 3 months treatment with supplements of 2 g n-3 PUFAs (*Calamarine*® 250/250TG) or placebo (olive oil) to examine the effects on HRV and arrhythmias recorded by 48 hours ambulatory ECG Holter monitoring.

Study population

Chronic dialysis patients at Aalborg University Hospital and Vendsyssel Hospital, Hjørring, Denmark. Sample size n=140.



Study Procedures



| Visit 1 (day 1) | Visit 2 (day 3) | Visit 3 (day 95) | Visit 4 (day 97) |
|-------------------------|-------------------------------|-------------------------|-----------------------------|
| Start Holter Monitoring | End Holter Monitoring | Start Holter Monitoring | End Holter Monitoring |
| ECG | | ECG | |
| Blood samples | | Blood samples | |
| Blood pressure | | Blood pressure | |
| Interview | | Interview | |
| Randomization | | | |
| | Begin Investigational Product | | End Investigational Product |

Perspective

If we are able to demonstrate a significant effect of n-3 PUFAs one might achieve a reduction in the risk of arrhythmias and by that possibly reduce morbidity and mortality in this high risk population by a cheap and well tolerated nutritional supplement.