

The Viborg Vascular (VIVA) randomised screening trial



Jes Lindholt

Professor of Vascular Surgery, DMSci, Ph.D.
Elitary Research Centre of Individualized Medicine in Arterial Diseases (CIMA)
Department of Cardiothoracic and Vascular Surgery T
Odense University Hospital, Denmark

Rikke Søgaaard

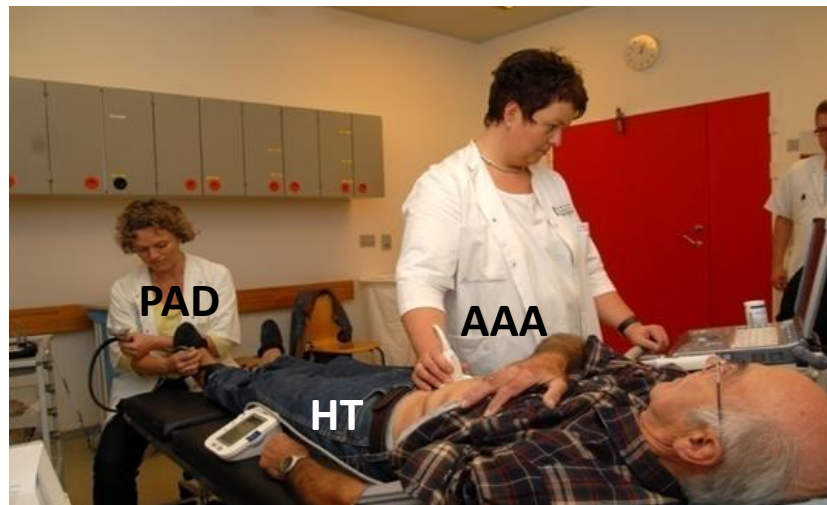
Professor in Health Economics, Ph.D.
Department of Public Health and Department of Clinical Medicine
Aarhus University
Denmark

Declaration of interest

- I have nothing to declare

Background and Primary aim

- Screening for CVD hasn't caught much attention
- To test whether *triple vascular screening* for abdominal aortic aneurysm (AAA), PAD and hypertension reduces overall mortality in 65-74 year old men
- Sample size calculation ≈ 50.000
 - RCT 1:1 based upon a relative risk reduction of 5%
 - 2 x 23,604 ($\alpha=5\%$, $\beta=90\%$)



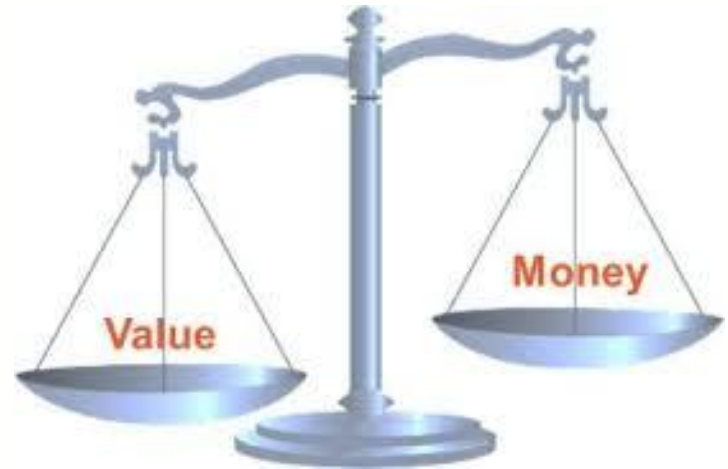
Triple vascular screening

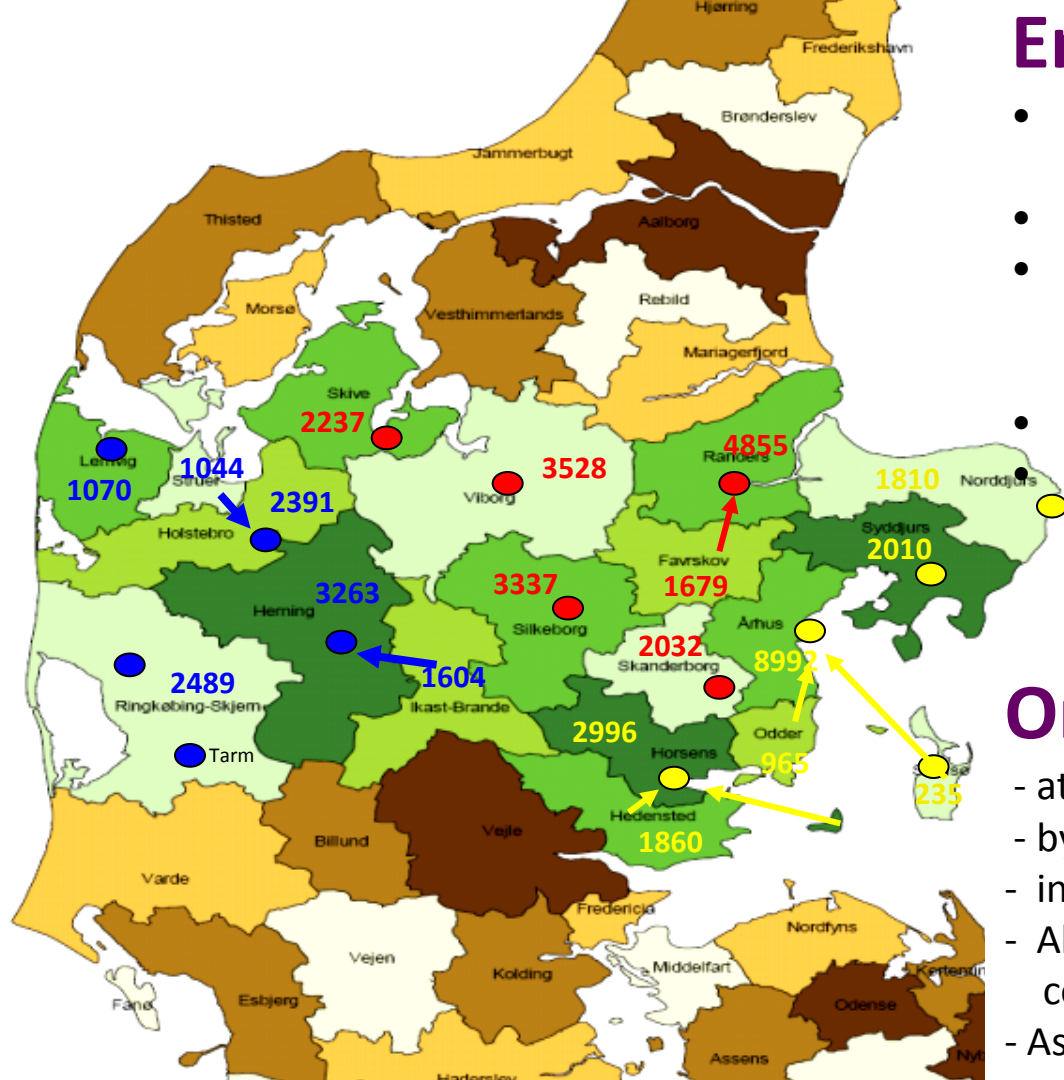
Declaration of interests: None

Protocol: Grondal N, Sogaard R, Henneberg EW, Lindholt JS. The Viborg Vascular (VIVA) screening trial of 65-74 year old men in the central region of Denmark: study protocol. *Trials* 2010; **11**: 67.

Secondary aims

- Many, but particular for health policy makers
 - Cost effectiveness
 - QoL consequences (EQ-5D)
 - Harms (diabetes, intracerebral haemorrhage, renal failure, cancer, and 30 d postoperative mortality after cardiovascular procedures)





Enrollment 2008-2011

- *Central Region of Denmark* – 1.2 million inhabitant (>1/5 of the Danish population)
- No exclusions: **All 50,168 men randomised**
- Computerbased randomisation secured concealment - stratified by the 16 municipalities
- The control group was masked
- Authors had no influence on- and were blinded for outcomes to date of analysis

- : Team East; 17,668
- : Team Mid; 17,636
- : Team West; 14,864

Organisation

- at 14 local hospitals/Health centres
- by 6 special-trained nurses
- in 3 mobile teams
- Abdominal US and Doppler-based ABI (Pic) + consultations of positive findings + controls
- Assisted by a secretary

Interventions of positive findings

- Men with an AAA (+30 mm)
- Men with PAD (ABI < 0.90 or > 1.4)



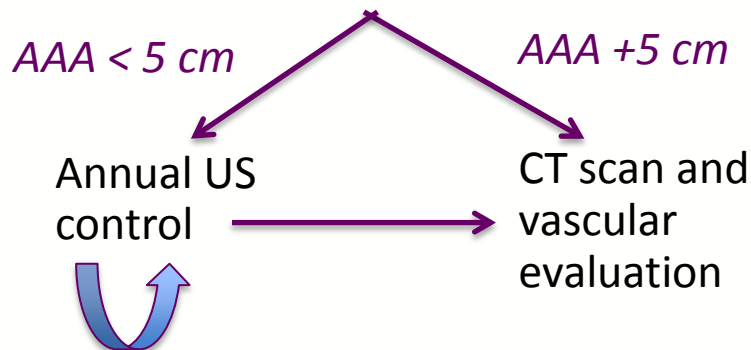
Nurse driven consultation for confirmation and initiation of preventive actions

- 75 mg Low dose aspirin
- 40 mg Simvastatin
- Instructions on diet, smoking cessation, and exercise.

Men with suspected moderate to severe hypertension (BP > 160/100 mmHG)



Referred for confirmation and treatment at G.P.



Five years after vascular triple screening for 65-74 year old men

- 7% lower overall mortality
- 169 needed to invite to save one life (NNI)
- € 2148 per gained QALY
- No serious negative side effects
(Postop deaths, CNS bleeding, DM, cancer, uraemia, QoL, overdiagnosing & overtreatment)
- *For clinicians:*
 - AAA & PAD patients ought to receive statins & antiplatelets
- *For health policy makers:*
 - Implement triple vascular screening of 65-74 year old men



**Online at
The Lancet**