Validation of Treating to Non-Fasting Lipid Targets in Comparison to Fasting Lipid Targets

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Current treatment targets for LDL-C, non-HDL-C and apo B can be used as accurately in the non-fasting state as in the fasting state. The measurement of LDL-C, non-HDL-C and apo B in the non-fasting state does not confer to an increased risk of...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26747

Bron
Nationaal Trial Register

Verkorte titel
NoFastLipidStudy

Aandoening

hyperlipidemia
hypercholesterolemia
secondary cardiovascular prevention
Fasting
non-fasting

Ondersteuning

Primaire sponsor: Albert Schweitzer Ziekenhuis
Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of patients that reach the set treatment target of LDL-C <2.5 mmol/l when using non-fasting blood samples while their fasting LDL is>2.5mmol/l.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Current guidelines recommend to measure the lipid profile in the fasting state although evidence is growing that a non-fasting lipid profile is sufficient most of the time and more convenient for both physicians and patients. However, comparisons between the absolute difference in fasting and non-fasting lipid profiles within individuals is lacking. Therefore, it is unknown whether current lipid treatment targets are suitable when using non-fasting lipid profiles.

Objective: To investigate whether a non-fasting lipid profile is as accurate and of equal clinical value as a fasting lipid profile for guiding lipid lowering therapy for secondary cardiovascular risk reduction.

Study design: Open randomized, cross-over trial where subjects are randomized between first measuring a fasting lipid profile followed by a non-fasting lipid profile on a separate day or vice versa.

Study population: Patients on lipid lowering therapy as secondary prevention for cardiovascular disease.
Main study endpoint: The number of re-classified patients that reach the treatment target of LDL-C <2.5 mmol/l when using non-fasting blood samples while their fasting LDL is >2.5mmol/l.

Risks, burden and benefits on participation: No major risks are involved besides a hematoma from the venipunctures or hypoglycemia due to fasting. Subjects need to visit the hospital two times, once fasting and, on another day, any time the subjects wish. During the two measurements it is not allowed to change lipid lowering therapy. Subjects receive an expense allowance of 10 euro’s upon participation. The potential benefit of the study is to demonstrate that a non-fasting lipid profile is accurate enough in comparison to a fasting lipid profile, which will ease the measurement of lipid levels for a large patient population worldwide.

Doel van het onderzoek

Current treatment targets for LDL-C, non-HDL-C and apo B can be used as accurately in the

non-fasting state as in the fasting state. The measurement of LDL-C, non-HDL-C and apo B in the non-fasting state does not confer to an increased risk of falsely reaching the recommended treatment target.

Onderzoeksopzet

Not-applicable

Onderzoeksproduct en/of interventie

Open randomized, cross-over trial where subjects are randomized between first measuring a fasting lipid profile followed by a non-fasting lipid profile on a separate day or vice versa.

Contactpersonen

Publiek

Department of Internal Medicine - Albert Schweitzer Ziekenhuis

Boudewijn Klop
P.O. Box 444

Dordrecht 3300 AK
The Netherlands
Tel: 078-6550545

Wetenschappelijk

Department of Internal Medicine - Albert Schweitzer Ziekenhuis

Boudewijn Klop
P.O. Box 444

Dordrecht 3300 AK
The Netherlands
Tel: 078-6550545

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Male and female patients, aged 18 years or older, from the outpatient department of Cardiology and Internal Medicine receiving lipid lowering therapy as secondary cardiovascular prevention are suitable for inclusion. Lipid lowering therapy is defined as the use of statins, fibrates, ezetimibe or nicotinic acid or a combination of these

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A change in lipid lowering therapy within the last 4 weeks is an exclusion criterium for study participation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	350
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-07-2015

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41824
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4819
NTR-old	NTR5321
CCMO	NL51908.101.14
OMON	NL-OMON41824

Resultaten

Samenvatting resultaten

1. Bansal, S., Buring, J. E., Rifai, N., Mora, S., Sacks, F. M., and Ridker, P. M. (2007) Fasting compared with nonfasting triglycerides and risk of cardiovascular events in women. JAMA.298, 309-316
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5. Nordestgaard, B. G., Benn, M., Schnohr, P., and Tybjaerg-Hansen, A. (2007) Nonfasting triglycerides and risk of myocardial infarction, ischemic heart disease, and death in men and women. JAMA.298, 299-308
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7. Klop, B., Cohn, J. S., van Oostrom, A. J., van Wijk, J. P., Birnie, E., and Castro Cabezas, M. (2011) Daytime triglyceride variability in men and women with different levels of triglyceridemia. Clin Chim Acta.412, 2183-2189
8. Sidhu, D., and Naugler, C. (2012) Fasting time and lipid levels in a community-based population: a cross-sectional study. Arch Intern Med.172, 1707-1710
9. de Vries, M., Klop, B., and Castro Cabezas, M. (2014) The use of the non-fasting lipid profile for lipid-lowering therapy in clinical practice - point of view. Atherosclerosis.234, 473-475
10. Khera, A. V., and Mora, S. (2012) Fasting for lipid testing: is it worth the trouble?: comment on "fasting time and lipid levels in a community-based population". Arch Intern Med.172, 1710-1711