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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26747

Source
Nationaal Trial Register

Brief title
NoFastLipidStudy

Health condition

hyperlipidemia
hypercholesterolemia
secondary cardiovascular prevention
Fasting
non-fasting

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis
Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

-The number of patients that reach the set treatment target of apo B <0.8 g/l when using non-fasting blood samples and do not reach the target in fasting blood samples.

-The number of patients who reach the set treatment target of non-HDL-C<3.3mmol/l when using non-fasting blood samples and do not reach the target in fasting blood samples.

-Differences in morning and afternoon LDL-C levels.

-Absolute differences in fasting and non-fasting LDL-C, direct LDL-C, apo B, non-HDL-C and triglycerides.
-Absolute differences between calculated LDL-C, direct LDL-C and LDL-C using ultracentrifuge in relation to the triglyceride concentrations.

-Construction of ROC curves to determine optimal normal values for non-fasting LDL-C.

Study description

Background summary

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.

Study objective

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.

Study design

Not-applicable

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	350
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-07-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41824
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results

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
3. Eberly, L. E., Stamler, J., and Neaton, J. D. (2003) Relation of triglyceride levels, fasting and nonfasting, to fatal and nonfatal coronary heart disease. Arch Intern Med.163, 1077-1083
4. Mora, S., Rifai, N., Buring, J. E., and Ridker, P. M. (2008) Fasting compared with nonfasting lipids and apolipoproteins for predicting incident cardiovascular events. Circulation.118, 993-1001
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
6. Langsted, A., and Nordestgaard, B. G. (2011) Nonfasting Lipids, Lipoproteins, and Apolipoproteins in Individuals with and without Diabetes: 58 434 Individuals from the Copenhagen General Population Study. Clin Chem.57, 482-489
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