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Value of Intermediate endpoints for Treatment in outpAtient cLinic: Nurse-led multi-factorial risk counselling intervention to improve adherence to lipid lowering medication and lipid levels versus routine clinical care in patients with an increased cardiovascular risk

Submission date 10/10/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 02/11/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/05/2015	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Reducing high blood levels of LDL cholesterol decreases the chances of getting a heart attack and other cardiovascular events both in people who have had previous heart attacks (secondary prevention) and in people who have risk factors but have not yet had a heart attack (primary prevention). Statins are drugs that treat high blood cholesterol levels. Many studies show that statins are effective in the primary and secondary prevention of heart attacks and other cardiovascular events. People need to take their statins as prescribed and not to miss doses for the drugs to work properly. Taking drugs as prescribed and not missing doses is called adherence. Many people find it hard to be adherent with their medications all the time. The aim of this study was to investigate if a nurse counselling people about their personal cardiovascular risk factors, including their actual cholesterol levels in the blood, and their personal risk of getting a cardiovascular event would improve adherence to statins without making people anxious.

Who can participate?
People aged 18 or older who are prescribed statins for prevention of cardiovascular disease.

What does the study involve?
Participants are randomly allocated to receive either medical care as usual or to receive additional counselling from a nurse about their personal cardiovascular risk factors.

What are the possible benefits and risks of participating?
The possible benefit of the additional counselling is that it may improve the participants' adherence with statin treatment and thereby lower (improve) the participants' blood cholesterol

levels. The possible risk of receiving the additional counselling is that receiving information about personal cardiovascular risk factors could make someone anxious about his or her risk of getting a cardiovascular event.

Where is the study run from?
Academic Medical Center and Slotervaart Hospital, Netherlands.

When is the study starting and how long is it expected to run for?
The study started in May 2002 and ended in May 2004.

Who is funding the study?
Pfizer, Netherlands.

Who is the main contact?
Prof. Erik Stroes
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Nurse-led multi-factorial risk counselling intervention to improve adherence to lipid lowering medication and lipid levels versus routine clinical care in patients with an increased cardiovascular risk: a randomised non-blinded two-centre controlled trial

Acronym
VITAL

Study objectives
Nurse-led multi-factorial risk counselling will result in improved adherence to lipid lowering medication and lipid levels compared with routine clinical care in patients with an increased cardiovascular risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Review Academic Medical Center Amsterdam, MECnr 01/156, approved the study on 20/03/2002 for the Academic Medical Center, Amsterdam, and on 27/06/2002 for the Slotervaart Hospital, Amsterdam.

Study design
Randomised non-blinded two-centre controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Patients were randomly assigned to receive routine care or extended care at baseline and at months 3, 9 and 18. Patients in the extended care group received a personalized risk factor passport, showing modifiable and un-modifiable individual risk factors and a graphical presentation of their calculated absolute 10-year cardiovascular disease risk as well as the target risk that could be reached if all modifiable risk factors were optimally treated.

Intervention Type
Behavioural

Primary outcome measure

1. Lipid levels: total cholesterol, triglycerides, higher-density-lipid cholesterol, and lower-density-lipid cholesterol
2. Adherence to lipid lowering medication in the past week (scale from 1 to 5), and in the past month (scale from 1 to 9)
3. Anxiety, assessed by the Hospital Anxiety and Depression Scale
Assessed at baseline and at months 3, 9 and 18.

Secondary outcome measures
1. Carotid intima-media thickness
2. Flow-mediated dilatation
3. Body Mass Index
4. Quality of Life (SF-12)
5. Symptoms (symptom checklist EORTC)
6. Beliefs about Medication Questionnaire (BMQ)
7. Risk perception (scale from 1 to 9)
8. Self-reported smoking status (yes/no)
9. Blood pressure, systolic and diastolic.

Carotid intima-media thickness and flow-mediated dilatation are assessed at baseline and at month 18. The other secondary outcomes are assessed at baseline and at months 3, 9 and 18.

Overall study start date
01/05/2002

Completion date
31/05/2004

Eligibility

Key inclusion criteria
1. Indication for statin therapy
2. Age >18 years
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Use of statin therapy > 3 months
2. Diabetus mellitus type II: fasting glucose >7,0 mmol/L
3. Fasting total cholesterol > 9,0 mmol/L
4. Fasting Triglycerides > 4,0 mmol/L
5. Liver function disturbances (ASAT/ALAT >2 times reference values)
6. Creatinine kinase (CK) elevations (>3 times reference values)
7. Drug and/or alcohol abuse
8. Pregnancy and breastfeeding
9. Life expectancy <2 years
10. Inability to fill out a Dutch questionnaire, because of problems with Dutch language

Date of first enrolment
01/05/2002

Date of final enrolment
31/05/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Center (Netherlands)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Pfizer Ltd (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration