Stichting Gezondheidscentra Eindhoven (SGE) Smoking Cessation Innovation.

Published: 24-11-2009
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Lifestyle issues
Study type	Interventional

Summary

ID

NL-OMON36281

Source
ToetsingOnline

Brief title
COVACO

Condition

- Lifestyle issues

Synonym
Smoking, tobacco use

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Pfizer,Pfizer;CAPHRI en SGE

Intervention

Keyword: Primary care, Randomized controlled trial, Smoking cessation, Varenicline

Outcome measures

Primary outcome

Prolonged absinence from smoking from week 9 through week 26. Exhaled carbon monoxide (CO) will be measured, CO-levels of <10ppm will be used as a biomarker of absinence.

Secondary outcome

Intervention costs per quitter

Cost-effectiveness ratio

Compliance with the use of varenicline

Study description

Background summary

Cigarette smoking is the most important contributor to the burden of disease in the Netherlands, responsible for approximately 13% of all disability adjusted life years lost. Despite the well-known health risks, 28% of the Dutch population still smokes today. An important measure to reduce smoking is to help more smokers to quit by increasing the efficacy and effectiveness of smoking cessation treatments.

Two distinct types of smoking cessation treatment are individual counselling and the use of varenicline, an α4β2 nicotine acetylcholine receptor partial agonist that reduces tobacco withdrawal symptoms and the reinforcing effects of smoking. In previous efficacy trials, varenicline was combined with intensive behavioural support and it is not clear what the single contributions to the overall efficacy of both types of treatments are. Although clinical guidelines state that the combination of medication and counselling is more effective than either treatment alone, the scientific evidence for this conclusion is scarce. Furthermore, no studies on individual counselling and varenicline have been performed so far under routine care conditions in the Netherlands. Yet, a study directly comparing single varenicline with the combination treatment of

varenicline and individual counselling is badly needed to evaluate the effects and the cost-effectiveness of both types of treatment in Dutch smokers.

Study objective

Our proposed randomized controlled trial is the first making this head-to-head comparison in a *real life* primary care setting in the Netherlands. The primary research question is: does a 12-week combination therapy of open label varenicline and individual counselling (group VC) increase the carbon monoxide validated prolonged smoking cessation rate from week 9 through 26, compared with 12 weeks single open label varenicline (group V) in adult daily cigarette smokers? A minimum of 272 daily smokers of 18 years of age or older with no contra-indications for the use of varenicline will be randomised to one of the two treatment groups.

Secondary research question 1 is: what are the short-term health and economic effects of smoking cessation? The short-term incremental cost-effectiveness of the combination treatment (group VC) compared with the single varenicline treatment (group V) will be expressed as additional costs per extra prolonged quitter from week 9 to 52, using group V as reference.

Secondary research question 2 is: what is the difference in compliance with the use of varenicline in group VC compared to group V? If the combination treatment of varenicline and individual counselling increases prolonged smoking cessation rates, it is important to understand the mechanisms that contribute to this effect. Increased compliance with the correct use of varenicline related to individual counselling may be one such mechanism.

Study design

This trial will be conducted within the Eindhoven Corporation of Primary Health Care Centres (SGE), which is a network of 10 primary care health centres covering approximately 60,000 patients (28% of the population of Eindhoven). Using the SGE allows testing of the treatments under real-life primary care conditions, which is key to assessing the effectiveness of the interventions and to future implementation of the trial results.

Intervention

The design of this study will be a randomized, parallel group, open label trial, comparing two intervention groups: the combination treatment of varenicline and individual counselling (group "VC") and single varenicline (group "V").
Participants from both group VC and group V will receive open label varenicline. The medication will be prescribed open label to test its

effectiveness under real life conditions, with smokers knowing that they receive active medication.

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

daily smoker
18 years of age or older

Exclusion criteria

Contra-indications for the use of varenicline

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-09-2011
Enrollment:	272
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Varenicline
Generic name:	Champix
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	24-11-2009

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-04-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-016446-50-NL
CCMO	NL30057.068.09