SGE Smoking Cessation Innovation.

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Intensive counselling from a practice nurse in combination with varenicline (intervention group) will be significantly more effective in smoking cessation than a short quit smoking advice from a general practitioner in combination with varenicline (...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23449

Bron
NTR

Verkorte titel
SGE SMR-innovatie

Aandoening

Smoking
Smoking cessation
Varenicline
Practice nurse
Intensive counselling
Health care innovation

Ondersteuning

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Overige ondersteuning: * Pfizer
* Stichting Gezondheidscentra Eindhoven (SGE)

* Research Institute CAPHRI

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Prolonged smoking abstinence from week 9 to week 26. Smoking abstinence will be validated by measuring exhaled carbon monoxide (CO) in all self-reported non-smokers.

Toelichting onderzoek

Achtergrond van het onderzoek

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 á4â2 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.

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 (intervention group) increase the carbon monoxide validated prolonged smoking cessation rate from week 9 through 26, compared with 12 weeks single open label varenicline (control group) 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 (intervention group) compared with the single varenicline treatment (control group) will be expressed as additional costs per extra prolonged quitter from week 9 to 52, using the control group 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.

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.

Doel van het onderzoek

Intensive counselling from a practice nurse in combination with varenicline (intervention group) will be significantly more effective in smoking cessation than a short quit smoking advice from a general practitioner in combination with varenicline (control group). We expect the prolonged abstinence rate from week 9 to 26 to be about 35% in intervention group and about 20% in the control group.

Onderzoeksopzet

1. Baseline;

2. Week 9;

3. Week 12;

4. Week 26;

5. Week 52.

Onderzoeksproduct en/of interventie

Participants in the intervention group recieve intensive counselling from a practice nurse in combination with 12-weeks varenicline. The intensive counselling consists of three individual face-to-face counselling sessions and seven telephone counselling sessions. The counselling sessions will be scheduled in week 1, 2, 3, 4, 5, 7, 12, 13 and 52. The overall counselling time will be 120 minutes. The timing and content of the counselling will be based on Dutch and international guidelines for smoking, cessation additional scientific evidence (for example about the relapse curves of non-aided quit attempts and quit attempts aided by varenicline), and input from patients and health care providers of SGE. State-of-the-art counselling techniques, including elements of motivational interviewing and cognitive behavioural therapy, will be incorporated in the counselling approach.

Participants in the control group recieve a short quit smoking advice from their general pracitioner (usual care) and 12-weeks varenicline.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

We aim to recruit those adult smokers into the trial who normally consult with their general practitioner in primary care.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Participants are excluded from the study when they:

1. Do not smoke daily;

2. Are younger than 18 years;

3. Are unable to understand Dutch sufficiently.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	20-09-2011
Aantal proefpersonen:	272
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-09-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2920
NTR-old	NTR3067
Ander register	MEC Maastricht University/AZM : 09-3-075
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A