

A comparison of Nicotine Replacement Therapy and Nicotine Replacement Therapy combined with the Minimal Intervention Strategy for smoking cessation in cardiovascular outpatients.

Submission date 29/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/11/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A comparison of Nicotine Replacement Therapy and Nicotine Replacement Therapy combined with the Minimal Intervention Strategy for smoking cessation in cardiovascular outpatients.

Study objectives

In the literature evidence exists that Nicotine Replacement Therapy (NRT) approximately doubles smoking cessation rates, regardless of the setting. The Minimal Intervention Strategy (MIS) is propagated by several health institutions, but its incremental effect to NRT in cardiovascular patients if performed by a nurse in an outpatient setting is not known. In this study it is hypothesised that the combination of C-MIS and NRT significantly decreases the number of smokers if compared with NRT alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

In the experimental arm: Nicotine Replacement Therapy (patches) and The Minimal Intervention Strategy (short behavioural counselling)

In the control arm: only Nicotine Replacement Therapy (patches)

Intervention Type

Mixed

Primary outcome measure

The primary endpoint of the study is smoking cessation at 12 months follow-up, as indicated by patient self-report and objectivated by urine cotinine levels.

Secondary outcome measures

Secondary endpoints are:

1. Changes in cognitions and smoking behaviour
2. Change in quality of life (generic and disease specific quality of life)
3. Adherence to NRT
4. Evaluation of the intervention

Overall study start date

01/09/2001

Completion date

01/05/2004

Eligibility**Key inclusion criteria**

Consecutive patients who attend the cardiological or vascular surgical outpatients clinic, have a diagnosis of atherosclerotic cardiac or arterial disease and who smoked until the cardiac event more than 5 cigarettes per day, will be included.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

365

Total final enrolment

385

Key exclusion criteria

1. Acute myocardial infarction in the month prior to randomisation
2. Unstable angina
3. Serious arrhythmia
4. Recent stroke
5. Skin allergy complicating the use of nicotine patches

Date of first enrolment

01/09/2001

Date of final enrolment

01/05/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

PO Box 22700

Amsterdam

Netherlands

1100 DE

Sponsor information

Organisation

The Netherlands Heart Foundation (The Netherlands)

Sponsor details

PO Box 300

Den Haag

Netherlands

2501 CH

+31 (0)70-3155514

research@hartstichting.nl

Sponsor type

Charity

Website

<http://www.hartstichting.nl/research>

ROR

<https://ror.org/05nxhgm70>

Funder(s)

Funder type

Charity

Funder Name

The Netherlands Heart Foundation (The Netherlands) (ref: NHF2000/B216)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Literature review	01/11/2003		Yes	No
Other publications	Cognitive changes related to smoking behaviour	01/06/2005		Yes	No
Other publications	Effect of patient preferences	01/08/2005		Yes	No
Results article		01/12/2006	08/11/2022	Yes	No