SMOKE study: evaluation of the effectiveness of an intensive SmokeStopTherapy in an outpatient clinic setting for patients with chronic obstructive pulmonary disease

Submission date	Recruitment status	Prospectively registered
12/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited 03/07/2009	Condition category Respiratory	[] Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr J. van der Palen

Contact details

Research Coordinator Medisch Spectrum Twente P.O. Box 50000 Enschede Netherlands 7500 KA

Additional identifiers

Protocol serial number

NTR103; Dutch Asthma Foundation: 3.4.01.67.

Study information

Scientific Title

Study objectives

- 1. The SmokeStopTherapy (SST) is twice as effective than the minimal intervention strategy for lung patients (LMIS) 12 months after the start of the intervention based on validated continuous abstinence rates in patients with chronic obstructive pulmonary disease (COPD)
- 2. After one year the SST is more cost-effective than the LMIS
- 3. The secondary aim was to investigate the prospective determinants of smoking cessation in patients with COPD within the two separate smoking cessation programmes. Based on the ASE model, it was expected that Attitude, Social Support and Self-efficacy would be important predictors within both interventions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

Interventions

- 1. Control group: minimal intervention strategy for lung patients (LMIS) the LMIS consists of individual counselling and telephone contacts which could be combined with pharmacological support at the patients own expense
- 2. Experimental group: SmokeStopTherapy (SST) the SST consists of both individual and group counselling, telephone contacts and bupropion free of charge. Additionally, patients can reenter the individual sessions after they experienced a lapse within three months after the start of the intervention (recycling) to prevent a total relapse.

Other sponsor's for this trial are:

- 1. Medisch Spectrum Twente, P.O. Box 50000, 7500 KA, Enschede, The Netherlands
- 2. Slotervaart Hospital, P.O. Box 90440, 1006 BK, Amsterdam, The Netherlands
- 3. Catharina Hospital, P.O. Box 1350, 5602 ZA, Eindhoven, The Netherlands

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. Biochemically validated (salivary cotinine) continuous abstinence rate (defined as validated abstinence at six months and twelve months after the start of the intervention)
- 2. Biochemically validated point prevalence abstinence rate at 12 months after the start of SmokeStopTherapy (point prevalence)

Key secondary outcome(s))

- 1. Quality of life, measured by the St. Georges's Respiratory Questionnaire
- 2. Lung function (FEV1, inspired vital capacity [IVC], FEV1/IVC, FEV1% predicted)
- 3. The frequency and severity of exacerbations. The following severity-scale will be used:
- 3.1. Mild exacerbation: increased use of pulmonary medication by more than two occasions within a 24 hour period on three or more consecutive days, compared to the stable situation
- 3.2. Moderately severe exacerbation:
- 3.2.1. Treatment with antibiotics and/or oral steroids
- 3.2.2. Evidence of a chest infection
- 3.2.3. An increase in symptoms and increased use of pulmonary medication by more than four occasions within a 24 hour period on three or more consecutive days, compared to the stable situation
- 3.3. Severe exacerbation: requirement of emergency hospital treatment/hospital admission
- 4. Disease-specific symptoms: breathlessness, coughing, sputum production and sputum colour. Symptom scores will be used to indicate the severity of the symptoms
- 5. Additional secondary data for economic evaluation (cost-effectiveness):
- 5.1. Number of visits at the outpatient clinic
- 5.2. Number of hospital-admissions and admission-days
- 5.3. Number of visits to the emergency room
- 5.4. Days lost of work
- 5.5. Medication costs (from pharmacy records)
- 5.6. Euroqol 5D

Completion date

31/12/2005

Eligibility

Key inclusion criteria

- 1. Outpatients of Medisch Spectrum Twente (Enschede), Slotervaart hospital (Amsterdam), or Catharina hospital (Eindhoven)
- 2. Current smoker
- 3. Motivated to quit smoking
- 4. Aged 40 75 years (1961-1826)
- 5. Clinically treated COPD. Moderate COPD (% predicted forced expiratory volume in one second [FEV1] = 50 69) or severe COPD (% predicted FEV1 less than or equal to 50 as defined by the American Thoracic Society (ATS) criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

Key exclusion criteria

- 1. Hypersensitivity for elements of Bupropion SR
- 2. (Past history of) serious psychiatric co-morbidity
- 3. Liver cirrhosis/alcoholism
- 4. (Past history of) epilepsy/fits
- 5. Tumour in the central nervous system
- 6. Quitting the use of alcohol and/or benzodiazepines during the course of the study
- 7. (Past history of) diabetes
- 8. Eating disorder(s)
- 9. Usage of monoamine oxidase inhibitors (MAO-inhibitors)
- 10. A serious other disease with a low survival rate
- 11. Not able to understand, read or write Dutch
- 12. Women who are pregnant, breastfeeding or intending to conceive during the course of the study
- 13. Participant of the COPE study in the Medisch Spectrum Twente

Date of first enrolment

15/02/2002

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Netherlands

Study participating centre Research Coordinator

Enschede Netherlands 7500 KA

Sponsor information

Organisation

Netherlands Asthma Foundation (Netherlands)

ROR

Funder(s)

Funder type

Industry

Funder Name

Comprehensive Cancer Centre (Netherlands)

Funder Name

GlaxoSmithKline (Netherlands)

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Funder Name

Stedendriehoek Twente (IKST) (Netherlands)

Funder Name

Netherlands Asthma Foundation (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Results article 01/05/2007 Yes No