

Dutch Belgian randomised lung cancer screening trial (NELSON)

Submission date 07/06/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 07/06/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/09/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Lung cancer is the leading cause of cancer death worldwide and accounts for approximately 28% of all cancer deaths worldwide. Despite advances in medical diagnostics and treatment, the outlook for lung cancer has not improved considerably during the last few decades. New developments in CT scanning have led to a renewed interest in lung cancer screening. Although studies have shown that screening reduces the number of lung cancer deaths, the cost-effectiveness, the best screening policy, and the balance between harms and benefits are still unknown. The aims of this study are: to investigate whether screening in a high-risk population leads to a reduction in lung cancer deaths of at least 25%; to estimate the impact of lung cancer screening on health-related quality of life and smoking cessation; and to estimate the cost-effectiveness of lung cancer screening for subgroups.

Who can participate?

People aged between 50 and 75 who were current smokers or former smokers who had quit smoking less than 10 years ago.

What does the study involve?

Participants are randomly allocated to either the screening or the control group. Screening group participants receive CT screening for lung cancer over several years, whereas participants in the control group receive no screening (usual care).

What are the possible benefits and risks of participating?

It is a feature of screening programmes that relatively few of the people who are invited for screening benefit from it, while a relatively large number of them will be exposed to minor unfavourable effects. In considering whether screening is justified, it is important to ensure that the favourable effects of screening (fewer deaths) should reasonably balance out the harms caused by screening (overdiagnosis, overtreatment, false-positive screening result, anxiety, discomfort etc). This will be investigated by this study.

Where is the study run from?

Department of Public Health, Erasmus MC, Rotterdam, The Netherlands. Participating centres: University Medical Centre Groningen, University Medical Centre Utrecht, Kennemer Gasthuis Haarlem (the Netherlands), and University Hospital Leuven (Belgium).

When is the study starting and how long is it expected to run for?

August 2003 to December 2015

Who is funding the study?

The Netherlands Organisation of Health Research and Development (ZonMw), the Dutch Cancer Society (KWF), and the Health Insurance Innovation Foundation (Innovatiefonds Zorgverzekeraars), Siemens Germany, Roche Diagnostics, G. Ph. Verhagen Stichting, Rotterdam Oncologic Thoracic Study (ROTS) group, Erasmus Trust Fund, Stichting tegen Kanker, Vlaamse Liga tegen Kanker, and LOGO Leuven.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR636

Study information

Scientific Title

Dutch Belgian randomised lung cancer screening trial (NELSON)

Acronym

NELSON

Study objectives

1. To establish in a randomised controlled trial if screening for lung cancer by multi-slice low-dose computed tomography (CT) in high risk subjects will lead to a 25% decrease in lung cancer mortality
2. To estimate the impact of lung cancer screening on health-related quality of life and smoking cessation
3. To estimate cost-effectiveness and help policy making

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Minister of Health approved the NELSON trial after a positive advice of the Dutch Health Council (22/11/2000), because of the Population Screening Act. Furthermore, the Medical Ethical committees of the participating centers (University Medical Centre Groningen, University Medical Centre Utrecht, Kennemer Gasthuis Haarlem [the Netherlands], and University Hospital Leuven [Belgium]) also gave their approval.

Primary study design

Interventional

Study design

Multicentre randomised active-controlled parallel-group trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Lung cancer

Interventions

1. Screen arm:
 - 1.1. 16-detector multi-slice computed tomography of the chest in year one, two and four of the study
 - 1.2. Pulmonary function test
 - 1.3. Blood sampling
 - 1.4. Questionnaires
 - 1.5. Smoking cessation advice for current smokers
2. Control arm:

Smoking cessation advice for current smokers.
3. A sample of controls:
 - 3.1. Pulmonary function test
 - 3.2. Blood sampling
 - 3.3. Questionnaires

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Lung cancer mortality (reduction)

Key secondary outcome(s)

1. Cost-effectiveness
2. Quality of life

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Born between 1928 and 1956
2. Smoked:
 - 2.1. More than 15 cigarettes per day for more than 25 years, or
 - 2.2. More than 10 cigarettes per day for more than 30 years
3. Current or former smokers who quit smoking less than or equal to 10 years ago

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Moderate or bad self-reported health who were unable to climb two flights of stairs
2. Body weight greater than or equal to 140 kg
3. Current or past renal cancer, melanoma or breast cancer
4. Lung cancer, diagnosed less than five years ago or greater than or equal to five years but still under treatment
5. Had a chest CT examination less than one year before they filled in the first NELSON questionnaire

Date of first enrolment

16/08/2003

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

Belgium

Netherlands

Study participating centre

Erasmus Medical Centre

Rotterdam

Netherlands

3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (Netherlands)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Research organisation

Funder Name

Vlaamse League Against Cancer (Vlaamse Liga tegen Kanker) (Netherlands)

Funder Name

Koningin Wilhelmina Fonds (KWF) (Netherlands)

Funder Name

Stichting Tegen Kanker

Alternative Name(s)

Fondation Contre le Cancer, Belgium Foundation Against Cancer, La fondation contre le Cancer

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Belgium

Funder Name

Erasmus Trust Fund (Netherlands)

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Funder Name

G. Ph. Verhagen Foundation (G. Ph. Verhagen Stichting) (Netherlands)

Funder Name

Siemens

Alternative Name(s)

Siemens AG, Telegraphen-Bau-Anstalt von Siemens & Halske

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Germany

Funder Name

Stichting Central Fund Reserves of Former Voluntary National Health Service Administration Insurances (Centraal Fonds van Voormalig Vrijwillige Ziekenfondsverzekeringen [RvvZ]) (Netherlands)

Funder Name

Rotterdam Oncology Thoracic Steering Committee (ROTS) (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	results	01/09/2007		Yes	No
Results article	patient participation results	01/09/2009		Yes	No
Results article	results on management of lung nodules	03/12/2009		Yes	No
Results article	results on health-related quality of life	01/07/2011		Yes	No
Results article	generalisability of results	01/07/2012		Yes	No
Results article	results	01/08/2012		Yes	No
Results article	complications results	01/09/2012		Yes	No
Results article	results	01/10/2012		Yes	No
Results article	follow-up results	20/05/2013		Yes	No
Results article	results	01/12/2013		Yes	No
Results article	results	01/11/2014		Yes	No
Results article	results	01/11/2014		Yes	No
Results article	results	01/01/2015		Yes	No
Results article	results	01/02/2015		Yes	No
Results article	results	01/04/2015		Yes	No
Results article	results	01/05/2015		Yes	No

Results article	results	01/08/2015	Yes	No
Results article	results	01/07/2016	Yes	No
Results article	results	15/07/2016	Yes	No
Results article	results	01/01/2017	Yes	No
Results article	results	01/08/2018	Yes	No
Results article	results	01/03/2019	16/05/2019 Yes	No
Results article	results	01/09/2018	25/09/2019 Yes	No
Other publications	2-year follow up data	01/07/2010	Yes	No
Other publications		01/08/2018	Yes	No
Study website	Study website	11/11/2025	11/11/2025 No	Yes