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Dutch Belgian randomised lung cancer screening trial (NELSON)

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

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?
Prof. Dr H.J. de Koning
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Study website
http://www.nelsonproject.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Multicentre randomised active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Lung cancer mortality (reduction)

Secondary outcome measures
1. Cost-effectiveness
2. Quality of life

Overall study start date
16/08/2003

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

Age group
Adult

Sex
Both

Target number of participants
15600

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)

Sponsor details
PO Box 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
University/education

Website
http://www.erasmusmc.nl/

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)
Belgium Foundation Against Cancer, 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)

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

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
Other publications	2-year follow up data	01/07/2010		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
Other publications		01/08/2018		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