Dutch Belgian randomised lung cancer screening trial (NELSON).

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1. To establish in a randomised controlled trial if screening for lung cancer by multi-slice low-dose 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...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22971

Bron
Nationaal Trial Register

Verkorte titel
NELSON

Aandoening

lung cancer

Ondersteuning

Primaire sponsor: - KWF Kankerbestrijding
- ZONMW
Overige ondersteuning: - Stichting Centraal Fonds Reserves van Voormalig Vrijwillige Ziekenfondsverzekeringen (RvvZ)
- Siemens Germany
- G. Ph. Verhagen Stichting
- Rotterdam Oncologic Thoracic Steering committee (ROTS)
- Erasmus Trust fund
- Stichting tegen Kanker
- Vlaamse Liga tegen Kanker

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Lung cancer mortality (reduction).

Toelichting onderzoek

Achtergrond van het onderzoek

Today, only 20% of lung cancers are at a resectable stage (stage I/II). 5-year survival is therefore low (15%). Computed Tomography (CT) screening detects more lung cancers than chest X-ray. It is unknown if this will translate into a lung cancer mortality reduction. The purpose of the NELSON trial is -to establish in a randomised controlled trial if screening for lung cancer by multi-slice low-dose CT in high risk subjects will lead to a 25% decrease in lung cancer mortality -to estimate the impact of lung cancer screening on health related quality of life and smoking cessation, and -to estimate cost-effectiveness and help policy making. Subjects with a high risk for lung cancer were first identified from the general population by sending a health questionnaire to approximately 500,000 men and women aged 50-74 in seven Dutch public health districts and 17 municipalities in Belgium. Eligible responders (n=30,134) were invited to participate. These were current smokers (55%) and former smokers (45%) who (had) smoked at least 16 cigarettes a day for at least 26 years or at least 11 cigarettes a day for at least 31 years. This was estimated to be the most optimal trial population. After giving informed consent (51.5%), 15,523 participants were randomised so far (1:1) to receive screening in year 1, 2 and 4 or usual care. The remaining 4,050 subjects needed to reach 80% power have been recruited in Denmark, and the Danish trial results will be uploaded at regular intervals to our database. CT screenings started in April 2004, performed with 16-detector multi-slice Spiral CT scanners and Siemens Lungcare® workstations and software for volumetric analyses. Both responders and trial participants appeared to be representative of the Dutch population of (heavy) current or former smokers. All baseline screenings and half of the second round screenings have at present been performed. At baseline screening, nodules have been categorised according to size and structure, at annual repeat screening according to the presence or absence of growth and according to volume doubling time (or being a new nodule). In the years 2007-2010 second and fourth year screens will be finalised. Lung cancer and all cause mortality in both study arms will be traced by linking our database to Statistics Netherlands and CBG. Causes of death of all lung cancer patients will be assessed by a review committee. Lung cancer cases, stages and tumor characteristics in both arms will be assessed by linkage to the regional cancer registries to estimate lead time and sensitivity. In a large subcohort quality of life around screening, assessment and diagnosis will be assessed. At 1 and 3-year follow up, smoking patterns and attitudes will be assessed. All smokers receive general or tailored

smoking cessation advice. Effects and costs will be estimated with a MISCAN model for lung cancer screening.

Doel van het onderzoek

1. To establish in a randomised controlled trial if screening for lung cancer by multi-slice low-dose 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.

Onderzoeksproduct en/of interventie

1. Screen arm:

a. 16-detector multi-slice computed tomography of the chest in year 1, 2 and 4 of the study;

b. Pulmonory function test;

c. Blood sampling;

d. Questionnaires;

e. Smoking cessation advice for current smokers.

2. Control arm:

smoking cessation advice for current smokers;

3. A sample of controls:

a. Pulmonory function test;

b. Blood sampling;

c. Questionnaires.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Born between 1928 and 1956;

2a. Smoked > 15 cigarettes/day during > 25 years or;

2b. Smoked > 10 cigarettes/day during > 30 years;

3. Current or former smokers who quit smoking =< 10 years ago.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects

1. With a moderate or bad self-reported health who were unable to climb two flights of stairs;

2. With a body weight >= 140 kilogram;

3. With current or past renal cancer, melanoma or breast cancer;

4. With lung cancer diagnosed less than 5 years ago or 5 years or more ago but still under treatment;

5. Who had a chest CT examination less than one year before they filled in the first NELSON questionnaire.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	16-08-2003
Aantal proefpersonen:	15600
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	22-03-2006
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	NL580
NTR-old	NTR636
Ander register	: N/A
ISRCTN	ISRCTN63545820

Resultaten

Samenvatting resultaten

- van Klaveren RJ, de Koning HJ, Mulshine J, Hirsch FR. Lung cancer screening by spiral CT. What is the optimal target population for screening trials? Lung Cancer 2002;38:243-52.

- van Klaveren RJ, Hirsch FR, van Iersel CA, Bunn PA. The selection of the optimal target population for spiral CT screening and chemoprevention trials. In: Hirsch FR, Bunn PA, Kato H, Mulshine JL, editors. Textbook of Prevention and Detection of Early Lung Cancer. Abingdon, Oxon, UK: Taylor & Francis; 2006. p. 361-384.

- van Iersel CA, de Koning HJ, Draisma G, Mali WPTM, Scholten ETh, Nackaerts K, Prokop M, Habbema JDF, Oudkerk M, van Klaveren RJ. Risk-based selection from the general population in a screening trial: selection criteria, recruitment and power for the Dutch-Belgian randomised lung cancer multi-slice CT screening trial (NELSON). Int J Cancer 2006; in press.