Prospective validation of the diagnostic accuracy of an automated asbestosis assessment

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21830

Source
Nationaal Trial Register

Brief title
PROSBEST

Health condition

Asbestosis

Sponsors and support

Primary sponsor: Investigator initiated study
Source(s) of monetary or material Support: Machiel van der Woude Stipendium from the Institute of Asbestos Victims located in the Hague, The Netherlands and Section Asbestos Related Diseases (SAGA) of the Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose (NVALT), Den Bosch, The Netherlands .

Intervention

Outcome measures

Primary outcome

The sensitivity of the AI- assessment procedure when assessing cases for financial asbestosis compensation in The Netherlands

Secondary outcome

1. The specificity, positive predictive value, negative predictive value and positive- and negative likelihood ratio of the AI- assessment procure when assessing financial cases for compensation for asbestosis in The Netherlands
2. The concordance of the asbestosis probability score between the AI- assessment and the judgment of 3 independent medical specialists
3. The sensitivity, specificity, positive predictive value, negative predictive value and positive- and negative likelihood ratio of the AI- assessment procedure when assessing the clinical diagnosis of asbestosis
4. The number of assessments in which the AI-assessment failed to provide an asbestosis probability score
5. The sensitivity specificity, positive predictive value, negative predictive value and positive- and negative likelihood ratio of the High Resolution AI- assessment procure when assessing financial cases for compensation for asbestosis in The Netherlands.

Study description

Background summary

Background: Asbestosis is a rare pneumoconiosis, which emerges after extensive occupational asbestos exposure. Financial compensation is possible in The Netherland if an independent pulmonologist panel underlines the diagnosis based on: Extensive asbestos exposure, the presence of lung fibrosis and loss of lung function. Since this is a time consuming and expensive process, an automated asbestosis assessment procedure was developed in which an artificial intelligence prediction model- and lung function loss is combined with medical experts assessments.

Objectives: The primary objective of this trial is sensitivity of the asbestosis automated assessment procedure. Main secondary objectives will be diagnostic accuracy in term of specificity, positive predictive value, negative predictive value and positive- and negative likelihood ratio.

Trial design: This prospective cohort study will include all Dutch applicants for asbestosis compensation from September 2020. All applications will be assesses by the standard workup (reference test), and parallel by the automated assessment procedure (index test). The two assessment strategies will be blinded for each other. Inclusion will be stopped after 59 patients are diagnosed with asbestosis by the reference test.
Ethics and dissemination: Approval of the study by the Institutional Review Board has been obtained prior to the start of this study. The aim is to report the study findings in international peer-reviewed journals and to present the data at international meetings.

Study objective

We hypothesize that the AI- assessment procedure will have a sensitivity of 98%.

Study design

The is a observational prospective cross-sectional study. Both the index test and the refference test will take place after registration of the application at the SAGA. Both the data for the primary and secondary outcomes will be collected at the time of reference test and the index test take place

Intervention

Observational study

Contacts

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Eligibility criteria

Inclusion criteria

All applications for financial asbestosis compensation at the Intituut Asbest slachtoffer (IAS) which are proceeded to the Sectie Asbest-Gerelateerde Aandoeningen (SAGA) from Oktober 2020 will be included in the consecutive validation cohort. Inclusion will be stopped after 59 patients are diagnosed with asbestosis by the reference test.

Exclusion criteria

All applications presided by the IAS will be taken into account for this model. However, IAS can decide to not proceed an application to the SAGA if: Patients already received compensation for asbestosis or malignant mesothelioma in the past or if the applicant was not a Dutch citizen for more than ten years.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	59
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9064
Other	Institutional Review Board of The Netherlands Cancer Institute : This study is not a subject to the Medical Research Involving Human Subjects Act (WMO), judged by the accredited Medical Research Ethics Committees of The Netherlands Cancer Institute (IRBd19-136)

Study results