# Psychosocial needs in patients and their partners after an abnormal chest X-ray

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**Ethical review** Approved WMO **Status** Recruitment stopped

**Health condition type** Miscellaneous and site unspecified neoplasms malignant and

unspecified

**Study type** Observational non invasive

# **Summary**

#### ID

NL-OMON34057

#### Source

ToetsingOnline

#### **Brief title**

Psychosocial needs in lung disease

#### **Condition**

Miscellaneous and site unspecified neoplasms malignant and unspecified

#### Synonym

lung cancer, lung carcinoma

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Universiteit van Tilburg

Source(s) of monetary or material Support: Ministerie van OC&W

#### Intervention

**Keyword:** Psychosocial needs, Quality of life

#### **Outcome measures**

#### **Primary outcome**

Quality of Life

**Anxiety** 

Depressive symptomen

Needs

#### **Secondary outcome**

niet van toepassing

# **Study description**

#### **Background summary**

In the rapid course of disease, lung cancer tends to focus on treating patients' physical symptoms, while psychosocial problems get less attention. In line with this, clinical trials have mainly focused on traditional endpoints, for instance, overall survival and disease-free survival. Given the relatively poor prognosis of patients with lung cancer, the inclusion of quality of life as a primary endpoint of treatment becomes increasingly important. Although there is paucity of research adressing the psychosocial aspects of lung cancer, an increasing recognition emerges regarding the importance of identifying the psychosocial needs of patients.

#### Study objective

The main objective of this study is to examine the incidence of psychosocial needs, anxiety and depressive symptoms at each time point, and to identify risk factors for worse short-term Quality of Life (QOL) in lung cancer patients and their partners. The role of sociodemograhphc, clinical and psychosocial factors on patient's and partners'QOL.

#### Study design

Observational cohort study

#### Study burden and risks

No risks, no benefits, limited burden (90 minutes within 3 months)

## **Contacts**

#### **Public**

Universiteit van Tilburg

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# **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Patients with an abnormality on thorax X-ray that raises suspicion of possible lung cancer Patients are 18 years or older Ability to provide written consent

#### **Exclusion criteria**

Psychiatric illness Patients who had thoracic surgery before Unable to respond to questions in Dutch

# Study design

## **Design**

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Other

#### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2011

Enrollment: 400

Type: Actual

# Medical products/devices used

Registration: No

# **Ethics review**

Approved WMO

Date: 30-08-2010

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 27-09-2010

Application type: Amendment

Review commission: METC Brabant (Tilburg)

# **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

CCMO NL32799.008.10