Smoking cessation by combined medication and counseling in lung cancer patients – effectiveness in a high prevalence real life setting

First published: 01/03/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS8748

Study ID

30127

DARWIN EU® study

No

Study countries

Germany

Study description

Smoking cessation is not only paramount in the prevention but also in the treatment of lung cancer. Indeed, survival in lung cancer is clearly influenced by persistent smoking. Unfortunately little data is available concerning smoking cessation and thus physicians are reluctant to recommend cessation in this setting. Our aim is therefore to evaluate a comprehensive smoking cessation intervention using pharmacotherapy and motivational interviewing in patients with newly diagnosed lung cancer. To understand the obstacles to patients of quitting smoking, depression as well as nicotine withdrawal symptoms will be evaluated. This is a monocenter, 12-week, prospective, observational, non-comparative trial performed at a large University lung cancer center. We assume that 80 patients are willing to participate with 90% being evaluated at 12 weeks. Smoking will be validated biochemically by exhaled carbon monoxide (CO). Nicotine withdrawal symptoms and depression will be evaluated by questionnaires. The primary endpoint is the abstinence rate at week 12 as based on biochemical verification. Secondary endpoints will be safety and 26-week data. The evaluations will be performed according to the intention-to-treat principle. Given previous experience of our group it will be possible to demonstrate the 12-week abstinence rate to be significantly above 45% with a power of at least 80% at a one-sided significance level of 5%. In conclusion this real life study will help to establish the effectiveness of combined medication and counseling in patients with lung cancer.

Study status

Finalised

Research institutions and networks

Institutions

Lungenfachklinik Immenhausen - Universitätsmedizin Göttingen English: Hospital for pulmonary diseases Immenhausen - University of Göttingen

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Stefan Andreas

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/12/2014

Study start date

Planned: 16/03/2015

Actual: 31/03/2015

Data analysis start date
Planned: 01/07/2018

Actual: 01/11/2018

Date of final study report
Planned: 28/02/2019

Actual: 06/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Pharma GmbH

Study protocol

TE-BC-Beobachtungsplan 27_11_2014.pdf (174.72 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To show that smoking cessation can be effectively and succesfully implemented in treatmend of patients with newly diagnosed lung cancer.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, observational, non-comparative trial

Study drug and medical condition

Medicinal product name, other

Nicotinell

Anatomical Therapeutic Chemical (ATC) code

(N07BA03) varenicline

varenicline

Population studied

Short description of the study population

Patients with verified diagnosis of lung cancer.

Inclusion criteria were as follows:

- Newly diagnosed lung cancer of all stages within 14 day of study enrollment

- Active smoking or smoking up to 4 weeks before study enrollment

- Age > 18 years

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Renal impaired

Estimated number of subjects

80

Study design details

Outcomes

Main abstinace rate at week 12 after smoking cessation, verified via measurement of exhaled carbon monoxide. Secondary endpoints will be 26-week abstinace rate as well as quality of life and depression.

Data analysis plan

Descriptive statistics of baseline variables will be generated. Abstinence rate at week 12 will be estimated and reported with exact 95% confidence intervals (Clopper/Pearson 1934). The analysis of the secondary endpoint 26-week abstinence rate will follow the same lines. The impact of depression on 12-week abstinence rates will be explored by calculating various trajectories of the longitudinal depression score, which will be included as independent variables in logistic regression models with 12-week abstinence rate as dependent variable. Similarly the association between depression and withdrawal symptoms will be investigated through linear models. Standard diagnostics will be applied to check adequate model fit. Regression coefficients will be reported with 95% confidence intervals and p-values testing the null hypothesis of no effect.

Documents

Study results

final_report_eupas8748.pdf (770.1 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No