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Trial record **1 of 196** for: PET Plan

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Radiotherapy Planning Based on Positron Emission Tomography With Fluoro-deoxyglucose For Advanced NSCLC (PET-Plan)

This study is currently recruiting participants.

Verified January 2012 by Arbeitsgemeinschaft Nuklearmedizin und Strahlentherapie der DEGRO und DGN

Sponsor:
Arbeitsgemeinschaft Nuklearmedizin und Strahlentherapie der DEGRO und DGN

Information provided by (Responsible Party):
Prof. Dr. Ursula Nestle, Arbeitsgemeinschaft Nuklearmedizin und Strahlentherapie der DEGRO und DGN

ClinicalTrials.gov Identifier:
NCT00697333

First received: June 11, 2008
Last updated: January 18, 2012
Last verified: January 2012
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Simultaneous radio-chemotherapy in advanced non-small cell lung cancer. The study focusses on a randomised comparison of conventional radiotherapy **planning** with irradiation of macroscopic tumor and lymph nodes together with prophylactic target volumes vs. irradiation only of FDG-positive lesions.

Primary endpoint is the local disease control in the chest.

Condition	Intervention	Phase
Non-small Cell Lung Cancer	Procedure: restriction of radiotherapy to FDG-**PET** positive areas only	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Optimisation of Radiotherapy-**Planning** in Patients With Inoperable Locally Advanced Non-Small-Cell Lung Cancer by FDG-**PET**

Resource links provided by NLM:

MedlinePlus related topics: Cancer Lung Cancer

U.S. FDA Resources

Further study details as provided by Arbeitsgemeinschaft Nuklearmedizin und Strahlentherapie der DEGRO und DGN:

Primary Outcome Measures:

- local progression free survival [Time Frame: actuarial] [Designated as safety issue: No]

Secondary Outcome Measures:

- Overall survival [Time Frame: actuarial] [Designated as safety issue: No]
- normal tissue toxicity [Time Frame: actuarial] [Designated as safety issue: Yes]

Estimated Enrollment: 394
Study Start Date: May 2009
Estimated Study Completion Date: February 2014
Estimated Primary Completion Date: August 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions

No Intervention: A Irradiation of all tumor manifestations detectable by CT and/or positron emission tomography using fluoro-deoxy-glucose including a part of eventual atelectasis and the whole affected lymph node stations by 60 - 74 Gy/2Gy) irradiation of elective lymph node stations up to 50 Gy/2 Gy	
Experimental: B Irradiation of all tumor manifestations detectable by positron emission tomography using fluoro-deoxy-glucose including the whole affected lymph node stations by 60 - 74 Gy/2Gy	Procedure: restriction of radiotherapy to FDG-**PET** positive areas only Restriction of target volumes to areas positive in positron emission tomography using fluoro-deoxy-glucose

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- histologically proved NSCLC
- UICC-stage I-III, no resection planned
- complete staging < 6 wks before treatment including cranial CT
- ECOG <3, Karnofsky-Index >60%
- age > 18 <
- FEV1 > 1,0 l or >35%
- RT-planning according to protocol feasible
- chemotherapy feasible
- written informed consent

Exclusion Criteria:

- neuroendocrine tumors, plain broncho-alveolar-cell ca.
- distant metastases, supraclavicular lymph node metastases
- malignant pleural effusion
- resection of actual tumor performed
- inclusion in other study protocol
- chemotherapy due to actual tumor before FDG-PET
- induction-chemotherapy
- acute vena cava superior syndrome
- second malignancy other than basalioma
- pregnancy, lactation
- heart insufficiency NYHA III/IV
- pneumoconiosis with active inflammatory changes of mediastinal lymph nodes
- acute broncho-pulmonary infection at time of PET-examination

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00697333

Contacts

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Locations

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Sponsors and Collaborators

Arbeitsgemeinschaft Nuklearmedizin und Strahlentherapie der DEGRO und DGN

Investigators

Principal Investigator: Ursula Nestle, PhD Universitätsklinikum Freiburg, Germany

More Information

Additional Information:

German site of the working group conducting this study EXIT

Publications:

Nestle U, Kremp S, Grosu AL. Practical integration of [18F]-FDG-PET and PET-CT in the planning of radiotherapy for non-small cell lung cancer (NSCLC): the technical basis, ICRU-target volumes, problems, perspectives. Radiother Oncol. 2006 Nov;81(2):209-25. Epub 2006 Oct 24. Review.

Nestle U, Schaefer-Schuler A, Kremp S, Groeschel A, Hellwig D, Rübe C, Kirsch CM. Target volume definition for 18F-FDG PET-positive lymph nodes in radiotherapy of patients with non-small cell lung cancer. Eur J Nucl Med Mol Imaging. 2007 Apr;34(4):453-62. Epub 2006 Oct 21.

Nestle U, Kremp S, Schaefer-Schuler A, Sebastian-Welsch C, Hellwig D, Rübe C, Kirsch CM. Comparison of different methods for delineation of 18F-FDG PET-positive tissue for target volume definition in radiotherapy of patients with non-Small cell lung cancer. J Nucl Med. 2005 Aug;46(8):1342-8.

Macmanus M, Nestle U, Rosenzweig KE, Carrio I, Messa C, Belohlavek O, Danna M, Inoue T, Deniaud-Alexandre E, Schipani S, Watanabe N, Dondi M, Jeremic B. Use of PET and PET/CT for Radiation Therapy Planning: IAEA expert report 2006-2007. Radiother Oncol. 2008 Dec 17; [Epub ahead of print]

Nestle U, Weber W, Hentschel M, Grosu AL. Biological imaging in radiation therapy: role of positron emission tomography. Phys Med Biol. 2009 Jan 7;54(1):R1-R25. Epub 2008 Dec 5.

Schaefer A, Kremp S, Hellwig D, Rübe C, Kirsch CM, Nestle U. A contrast-oriented algorithm for FDG-PET-based delineation of tumour volumes for the radiotherapy of lung cancer: derivation from phantom measurements and validation in patient data. Eur J Nucl Med Mol Imaging. 2008 Nov;35(11):1989-99. Epub 2008 Jul 26.

Responsible Party:	Prof. Dr. Ursula Nestle, Prof. Dr. Ursula Nestle, Universitätsklinikum Freiburg, Arbeitsgemeinschaft Nuklearmedizin und Strahlentherapie der DEGRO und DGN
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Keywords provided by Arbeitsgemeinschaft Nuklearmedizin und Strahlentherapie der DEGRO und DGN:
NSCLC
FDG-**PET**
Radiotherapy
planning
target volumes

Additional relevant MeSH terms:

Carcinoma, Non-Small-Cell Lung	Respiratory Tract Diseases
Lung Neoplasms	Deoxyglucose
Carcinoma, Bronchogenic	Antimetabolites
Bronchial Neoplasms	Molecular Mechanisms of Pharmacological Action
Respiratory Tract Neoplasms	Pharmacologic Actions
Thoracic Neoplasms	Antiviral Agents
Neoplasms by Site	Anti-Infective Agents
Neoplasms	Therapeutic Uses
Lung Diseases	

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