

DEGRO AG Stereotaxie



Lungtech-RETRO: SBRT for central lung tumors

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PROJEKT- OUTLINE: „LUNGTECH - RETRO“ - RATIONALE

- Despite recently published data of RTOG 0813 the safety and efficacy of SBRT in central tumors remains unclear.
- Data for evaluating **the tolerance of mediastinal structures** is of high interest.
- Single centre series are far too small to draw any conclusions, huge retrospective database analyses often lack important information.

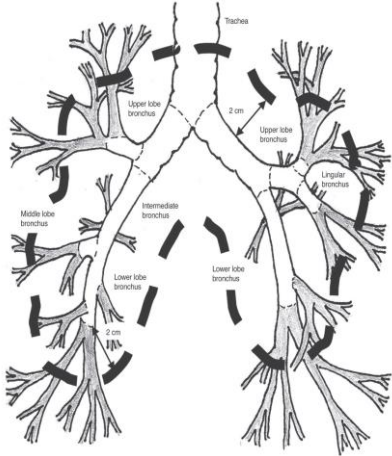
EORTC 22113-8113 LUNGTECH-TRIAL

SBRT of central NSCLC: 8X 7.5Gy = 60Gy

Primary Endpoint:
Freedom of local progression rate at 3 years

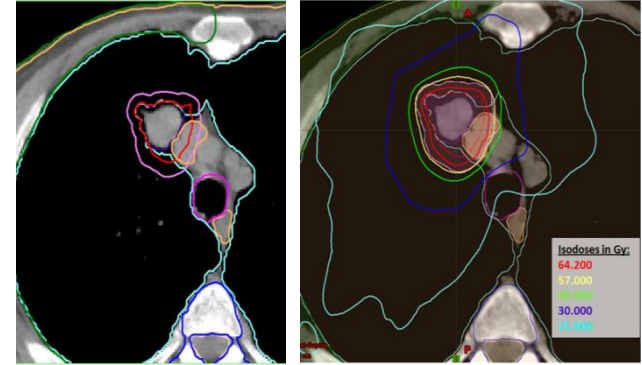
Secondary Endpoints:

- Toxicity
- Pattern of recurrence
- Overall survival
- Causes of death



--- Defines Zone of the Proximal Bronchial Tree

Timmerman et al, JCO 2006

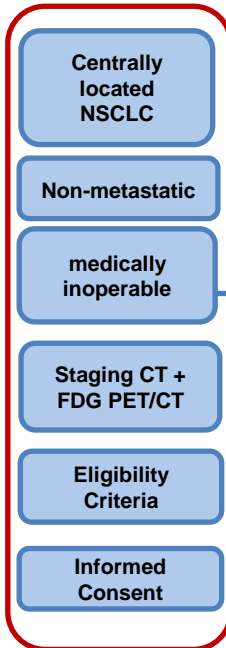


Modif. from Adebahr et al, BJR 2015

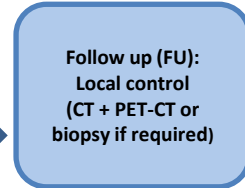
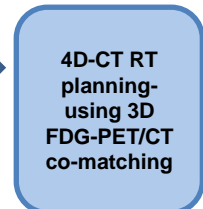
23 EORTC-Centers



INCLUSION



Central Review



*FU: 6 weeks after SBRT,
year 1-3: 3 monthly visits
year 4-5: 6 monthly
until end of the trial: yearly*

EORTC 22113-8113 LUNGTECH-TRIAL

SBRT of central NSCLC: 8X 7.5Gy = 60Gy

Primary End Point

- Between 08/15 and 12/17 inclusion of 39 pat.
- 2 stops of accrual due to strict stopping rules when potential “toxic deaths” had to be excluded
- Early stop of recruitment in 12/17 , ‘Follow up ongoing
- Thus ,patients with central lung tumors have been treated in analogy to the study protocol or with some modified treatment schedules
- A pooled analysis might lead to further insights on **toxicity and safety of SBRT for central and “ultra-central” lung tumors** and might even enable to **specify dose-effect correlations.**

*FU: 6 weeks after SBRT,
year 1-3: 3 monthly visits
year 4-5: 6 monthly
until end of the trial: yearly*

Consent

PROJEKT- OUTLINE: „LUNGTECH - RETRO“

OBJECTIVE:

To establish a database of patients with **centrally and ultra-centrally located lung tumors (NSCLC and pulmonary metastases** of otherwise controlled primaries in 2 separate approaches) treated with **highly conformal, dose-escalated image-guided radiotherapy techniques** to retrospectively analyze **the toxicity and dose-effect correlations for mediastinal risk organs**, as well as **efficacy of SBRT** in these patients .

Primary endpoint:

- Acute and late toxicity

Secondary endpoint(s):

- Freedom from local progression at three years after start of SBRT
- Patterns of local and distant recurrence , local progression free survival
- Overall survival and cause of death
- Dose-effect correlations for mediastinal risk organs (subproject).

Endpoint analysis will be performed separately for NSCLC and pulmonary lesions.

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➤ Key Eligibility criteria for SBRT patients:

- Indication and performance of SBRT in patients with **centrally located** (defined as tumor within 2 cm or touching the zone of the proximal bronchial tree or tumor that is immediately adjacent to the mediastinal or pericardial pleura, with a PTV expected to touch or include the pleura mediastinal) **early stage NSCLC OR pulmonary metastases** of an otherwise controlled primary tumor.
- Lesions confirmed by either histology or cytology or clear imaging signs (CT-suspicion, growth, FDG uptake) of malignant tumors
- No previous radiation from the thorax and / or mediastinum
- No chemotherapy or targeted therapy within 3 months before SBRT onset.
- No other malignancies, except adequately treated basal cell carcinoma or other malignancies, of which the patient has been disease-free for at least 5 years. If there is histological confirmation of NSCLC, 2 years of malignancy are sufficient for inclusion.
- Patients must have received a Biologically Effective Dose (BED) of at least 50 Gy ($\alpha/\beta= 10$; minimum EQD-2 ≥ 41.7 Gy) with highly conformal, image-guided radiotherapy techniques
- Any fractionation ≤ 8 is acceptable, as long as the BED is 50 Gy or more (EQD-2 ≥ 41.7 Gy)

„LUNGTECH - RETRO“ : SURVEY AG STEREOTAXIE

Is your center interested to participate in the project ?

SITE	Number of patients	Treatment plans
Uniklinik Jena		
Institut für Strahlentherapie Klinikum Fulda	5	+
Strahlentherapie Sued, Kaufbeuren	5-10	+
Radiation Oncology LMU	10	+
Charité Benjamin Franklin	10	+
Department of Radiation Oncology, University of Lübeck	20	+
Klinik für Strahlentherapie, Klinikum Bayreuth	5	+
Klinik für Strahlentherapie und Radioonkologie Schwarzwald-Baar-Klinikum Villingen-Schwenningen	<5-10	+
Strahlentherapie Bocholt	5	+
Medical School Hannover	15-20	-
Robert-Janker Klinik Bonn	10-15	+
UK Dresden	10-30	+
Strahlentherapie am Klinikum Passau / MVZ Radio-log Strahlentherapie am Klinikum Passau	5/ 5	+/ +

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SITE	Number of patients	Treatment plans
Charité Universitätsmedizin Berlin	10-20	+
Universitätsklinik Marburg, Klinik für Strahlentherapie	10	+
Universitätsklinikum Augsburg, Klinik für Strahlentherapie und Radioonkologie	10-15	+
Mannheim	30	+
Curavid - Strahlentherapie und Radiologie Lübeck	50-100	+
Klinik für Strahlentherapie, Heidenheim	5	
GSR Hannover	3-5	-
TUM Radonk	20	+
Saphir/Kiel	5	+
Freiburg	20	+
Policlinico Universitario di Modena	20 + 30-50	
University Hospital of Bern	90	+
Radioonkologie, Landeskrankenhaus, Salzburg at	12-18	-
Strahlentherapie und Radioonkologie Innsbruck/ RADIOONKOLOGIE-STRAHLENTHERAPIE Innsbruck	10/ 15	+/ +
Bank of Cyprus oncology center Cyprus	5-10	+

+ 8 Lungtech sites

~ 50

?

~600

~450

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To be done / discussed:

- PI will provide ethical approval (for the whole project), project plan.

- PI will send around an Excel database to collect data (within 4 months):
 - Baseline characteristics
 - SBRT data (RT and Dose-/volume information for OAR and for target volumes)
 - Outcome data: acute toxicity, late toxicity, LC, PFS, OS
 - if agreed, the treatment plan needs to be provided

- Collecting data and RT-plans (4-6 months)

- Analyses and drafting of manuscript
All participating center are very welcome to participate in the analysis, review the results in detail and access the central database at the PIs center upon request and available schedules.

- Publication:
All clinics providing data can name one co-author on each publication; clinics providing ten or more patients can name 2 co-authors on each publication.
As based on the AG guidelines.
For each project plan sub-analysis a publication may arise.

PROJEKT- OUTLINE: „LUNGTECH - RETRO“

Discussion/ Questions:

- Time Frame ok ?
- Further analyses and subprojects?
- Eligibility criterion:
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Diskussion/ Vorschläge aus Publikum:

- Dosis nicht begrenzen, bis 12 Fraktionen zulassen.
- Cut off hinsichtlich zeitlichem Einschluss definieren, modernes Kollektiv
- Bestrahlungsparameter von Beginn an detailliert erfassen
- Für Analyse der Pläne: Konturierung muss ohnehin durch PI kontrolliert werden,
Nachkonturierungen erfolgen dann von dort aus einer Hand, für aktuell definierten
Fragestellungen Freiburg
- Heidelberg, Würzburg und Zürich bekunden neben survey ebenfalls Interesse an Teilnahme

Herzlichen Dank

für Ihre Aufmerksamkeit!

