**Study**

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<th>A Phase I/II Study of Hypofractionated Proton Therapy for Stage II-III Non-Small Cell Lung Cancer</th>
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**Principle Investigator**

Brad Hoppe, MD

**Contact**

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**Additional Info**

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

NCT01770418

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**Recruitment Status**

1. Study Start Date: March 2013
2. Estimated Study Completion Date: 
3. Estimated Primary Completion Date: January 2038
4. Estimated Enrollment: 61
5. Recruiting

**Study Purpose**

The purpose of this research study is to compare the effects (good and bad) on subjects and their cancer using standard chemotherapy in combination with hypofractionated proton radiation therapy. Hypofractionation is a technique that delivers higher daily doses of radiation over a shorter period of time.

**Primary Aims**

- **Phase I**: Establish the maximum tolerated dose of radiotherapy in terms of Gy (RBE)/fraction using hypofractionated proton therapy concurrently with chemotherapy. [Time Frame: Weekly until completion of radiation treatment] [Designated as safety issue: Yes]
- This phase will have a minimum of 2 treated patients and we anticipate that the MTD will be located before a maximum of 28 patients are treated. The trial begins by treating 5 patients at 2.5 Gy (RBE)/fraction to a dose of 60 Gy (RBE).
- **Phase II**: Determine the percentage of patients that survive at least 12 months [Time Frame: At 12 months] [Designated as safety issue: No]
### Study

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### Secondary Aims

- Assess acute and late adverse events of concurrent chemotherapy with hypofractionated proton therapy. [Time Frame: On average every 3 months for 5 years] [Designated as safety issue: Yes]
- Analyze for disease control and overall survival. [Time Frame: At 2 years and 5 years] [Designated as safety issue: No]
- To assess cost-effectiveness of this hypofractionated treatment course. [Time Frame: At 2 and 5 years] [Designated as safety issue: No]

### Methods

**Experimental:** ProtonRadiotherapy with Chemotherapy  
**Radiation:** Radiation Concurrent Chemotherapy  
RADIATION: Proton Radiotherapy  
Dose Level 1: 60 Gy (RBE) at 2.5 Gy(RBE) per fraction x 24 fractions  
Dose Level 2: 60 Gy (RBE) at 3 Gy (RBE) per fraction x 20 fractions  
Dose Level 3: 60.01 Gy (RBE) at 3.53 Gy (RBE) per fraction x 17 fractions  
Dose Level 4: 60 Gy (RBE) at 4 Gy (RBE) per fraction x 15 fractions  
**CONCURRENT CHEMOTHERAPY:**  
Paclitaxel and Carboplatin or Cisplatin and Etoposide  
Paclitaxel at a dose of 45 mg/m² and carboplatin at a dose of AUC 2 mg/min/ml (a total of 3-5 weekly doses)  
OR  
Cisplatin 50mg/m² days 1, 8, 29, and 36 and etoposide 50mg/m² days 1-5, 29-33.  
Adjuvant chemotherapy is optional but encouraged.
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| **Eligibility** | Ages Eligible for Study: 18 Years and older  
Genders Eligible for Study: Both  
Accepts Healthy Volunteers: No  
**Criteria**  
Inclusion Criteria:  
- Pathologically confirmed invasive non-small cell lung cancer diagnosed within 12 weeks prior to study registration.  
- AJCC (American Joint Committee on Cancer) 7th Ed. clinical stage II-III.  
- ECOG Performance status 0-1 within 8 weeks prior to study registration.  
- Patient must give study-specific informed consent on an IRB-approved consent prior to any research-related procedures or study treatment.  
- Patient must be at least 18 years old at the time of consent.  
- Patient must complete all required tests in section 4.  
- Lab results per the following within 4 weeks prior to study registration:  
  - Absolute neutrophil count (ANC) >1,800 cells/mm3.  
  - Platelets \( \geq 100,000 \) cells/mm3.  
  - Hemoglobin \( \geq 10 \) g/dl. The use of transfusion or other intervention to achieve Hgb \( \geq 10.0 \) g/dl is acceptable.  
  - AST/SGOT and ALT/SGPT < 2.5 \( \times \) the institutional upper limit of normal (IULN).  
  - Post exploratory thoracotomy must be done \( > 3 \) weeks prior to study registration or patient did not have post exploratory thoracotomy  
  - PFT (pulmonary function test) with a FEV1 > 1 liters/second within 16 weeks prior to study registration. |
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| **Exclusion Criteria** | • Evidence of distant metastasis (M1) involvement.  
• Prior radiotherapy to thoracic area.  
• Unintentional weight loss >10% within 4 weeks prior to study registration.  
• Previous or concomitant malignancy within 3 years other than:  
  • Curatively treated carcinoma in situ of the cervix, breast, or oral cavity.  
  • Basal or squamous cell carcinoma of the skin.  
  • Curatively treated superficial transitional cell carcinoma of the urinary bladder.  
  • Low risk (T1c-T2a and PSA<10ng/ml and Gleason score <7) prostate cancer.  
• Other early stage tumor treated more than 2 years ago for cure.  
• Prior tumor resection.  
• On home oxygen therapy (intermittent or continuous).  
• Pregnant and/or breast-feeding women, or patients (men and women) of child-producing potential not willing to use medically acceptable forms of contraception while on study treatment and for at least 12 months after study treatment. Pregnancy testing is not necessary for women who have had a hysterectomy or have not had a menstrual period for at least 24 consecutive months. Please document as such. |