Pseudo-progression rationale for "ir"
Location

- The tissue specimen must be locatable on the imaging modality
  - Biopsy clip
  - Issues: artifact, timing, migration
  - Anatomic description
  - i.e. rectal biopsy at 5cm from AV, 12:00
  - Tumor heterogeneity
This page contains information on SBRT planning for non-small cell lung cancer (NSCLC) patients. SBRT, which makes them more prone to develop radiation-induced lung damage, utilizes non-coplanar beams to selectively avoid dose to ventilated lung regions with existing ventilation defects.
Title: Functional Lung Assist in Non-Coplanar Lung SBT with Hyperspectral X-ray CT

Phase 1

Working hypothesis: Hyperspectral x-ray CT adds valuable information of ventilation validity in lungs. A significant proportion of non-coplanar SBT patients, undergoing SBT planning, have failed validity, due to CO2, which may not be visible or invisible to clinicians. Hyperspectral imaging facilitates SBT planning, allowing clinical teams to evaluate absolute validity via SBT planning, which may add a new dimension to SBT planning.

Purpose: To determine the feasibility of using hyperspectral imaging for improving the validity of non-coplanar SBT planning.

Methods: The study uses hyperspectral imaging to evaluate the validity of non-coplanar SBT planning. The imaging data is compared with traditional planning methods to assess the added value of hyperspectral imaging.

Results: The study demonstrates a significant improvement in the validity of non-coplanar SBT planning using hyperspectral imaging.

Conclusions: Hyperspectral imaging is a valuable tool for improving the validity of non-coplanar SBT planning.

Working hypothesis: Hyperpolarized Xe-129 MRI yields spatially accurate information of ventilation defects in lungs. A significant proportion of non-small cell lung cancer (NSCLC) patients undergoing SBRT face existing ventilation defects due to COPD, which makes them more prone to develop radiation-induced respiratory symptoms. An non-operative SBRT planning utilized non-operative forced expiratory volume to selectively minimize radiation dose to ventilated lung volume, which may limit radiation-induced respiratory symptoms.

Primary study objective: To demonstrate that an non-operative lung volumetric body (AOE) planning incorporating lung ventilation data acquired with hyperpolarized (HPI) xenon (Xe) magnetic resonance imaging (MRI) can selectively avoid dose to ventilated lung volume in decline non-operative patients with existing ventilation defects.

Secondary study objective: NA

Brief justification (background and rationale—include up to 3-5 references)
Working hypothesis: Hyperpolarized Xenon MR yields spatially accurate information of ventilation defects in lungs. A significant proportion of non-small cell lung cancer (NSCLC) patients undergoing SBRT have existing ventilation defects due to COPD, which makes them more prone to develop radiation-induced respiratory symptoms. 4m non-coplanar SBRT planning utilizes non-coplanar beams to selectively minimize radiation dose to ventilated lung volume, which may limit radiation-induced respiratory symptoms.

Primary study objective: To demonstrate that 4m non-coplanar lung stereotactic body radiotherapy (SBRT) planning incorporating lung ventilation data acquired with hyperpolarized (HP) xenon (129Xe) magnetic resonance imaging (MRI) can selectively avoid dose to ventilated lung volume in chronic obstructive pulmonary disease (COPD) patients with existing ventilation defects.

Secondary study objective(s): N/A

Brief justification (background and rationale – include top 3-5 references):
Hypothesis: Hypothesized factors that yield accurate information of ventilation defects in lungs. A significant proportion of non-small cell lung cancer (NSCLC) patients undergoing SBRT have varying ventilation defects due to COPD which makes them prone to develop radiation-induced respiratory symptoms. We aim to improve SBRT planning accuracy using non-invasive passive detectors to accurately detect radiation-induced defects. We hypothesize that radiation-induced radiation defects can be detected using these detectors.

Primary study objectives: To demonstrate that non-small cell lung cancer patients undergoing SBRT treatment can be accurately detected using non-invasive passive detectors.

Secondary study objectives: To evaluate the effectiveness of non-invasive passive detectors in detecting radiation-induced radiation defects.

Methodology: The study will involve a cohort of NSCLC patients undergoing SBRT treatment. Non-invasive passive detectors will be used to detect radiation-induced radiation defects. The results will be compared with traditional imaging techniques to evaluate the accuracy and effectiveness of the non-invasive passive detectors.
in conceptual and reimbursement paradigms in oncology.

irradiated and unirradiated lesions at 6 weeks post injection. What assessment? If yes, how will quality be assured?

vital facility with high volume experience performing oncologic

phase I with 6 bins of 3 patients each, expanded to at least 6

approved data collection/management plan? No, but dose each is an established practice for phase I trials. An

lower dose level until biological activity or toxicity is also under would begin low and double per upward step. 
Title: Neuron Boost to GTV followed by primary photon(s)

Phase: I

Working hypothesis: Neuron boost prior primary photon(s) would address the high level of hypoxia in the GTV, causing the tumor to be more responsive to chemotherapy.

Primary study objective:

Secondary study objective(s):

Brief justification (background and rationale -- include top 3-5 references):

Eligibility:
Phase I:

Primary study objective:

Eligibility:

Treatment/intervention:

Secondary study objective:

Brief justification (background and rationale) – include top 3-5 references:

Selection criteria:

Inclusion criteria:

Exclusion criteria:

Neuromorphic circuit primary physics would address the high level of precision in the OCT, causing the fusion to be more responsive to...

CONNECT/DESCRIPTION.
Protocol deviations impact survival and toxicity

- H&N
  - RTOG 02.02*: 3-y OS 70% vs. 50% (Potera et al/COG 2010)
  - RTOG 01.02: 8-y OS 83% vs. 51% AV 41% vs. 10% (Wolfgang et al/COG 2014)
  - RTOG 00.22*: 2-y LFS 6% vs. 80% (Elmas et al/JRCP 2010)

- Parotid
  - RTOG 97.04*: GB 1.74 vs. 1.96 yrs and tumor Gr 4/8 non-home tox in early am (Ahn et al/JRCP 2012)
  - RTOG 05.13*: Gr 3; Gr 4: vs. 15% (Crane et al/CIO 09)

- Early-stage Hodgkin's
  - HD4*: 7-yr EFS 84% vs. 72% (Dhur niekt et al/CIO 001)
Protocol deviations due to inadequate target delineation:

- 33% of deviations due to "inadequate target delineation"
- 33% due to "major deviations"
- 10% due to "errors"
- 10% due to "inadequate delineation"
- 10% due to "inadequate target mismatch"
- 5% due to "delineation issues"
Our website!
eContour.org
Registration is FREE!
Systemic versus tissue parameters:
- Blood
- Tissue
- Other fluid analyses
- Microbiome
Flow analysis of immune cells

- More extensive profiling of immune cells
- Time consuming
- Inter-sample variability
Biomedical informatics: component sciences & technological relationships

Computer science

Information & communication sciences

Cognitive & social sciences/humanities

Mathematical, statistical, and decision sciences

Engineering

Biological & physical sciences
Particle Beam Based Clinical Applications for Radiation Oncology

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Presented at CRSO Clinical Trials Course
March 21-22, 2013
Washington, DC
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Presented at OHSU Clinical Trials Course
Date and Time: Saturday May 6, 2016 9:05-9:45am
Location: Portland, OR
Particle Beam Based Clinical Trial Design for Radiation Oncology

Ramesh Rengan, M.D. PH.D.

[Projector screen showing technical content related to particle beam designs in clinical trials for radiation oncology]
Particle Beam Based Clinical Trial Design for Radiation Oncology

Ramesh Rengan, M.D. Ph.D.

[Further content not visible in the image]
Learning Objectives

- At the conclusion of this session, participants will have a better sense of how mathematical modeling can be used in the design of radiation protocols and research.
- We will discuss how models can help develop new intermediate biomarkers (based on imaging).
- Then we will show the ability to use similar models.
Three categories for diagnosis and treatment

Quantitative Measures
Generated within Medical Laboratories

Quantitative Measure
Generated outside Medical Laboratories

Qualitative Measures
Ascertained by Trained Physicians

Cancer, Infectious Diseases

Diabetes, Asthma

Neurologic and Psychiatric Syndromes
Early steps

- Establish the team
  - Biostats – establish sample size
  - Surgeons, MedOnc, Pathology, Radiology, etc.

- Patient population
  - Do we see enough patients in clinic for this trial to be feasible?
  - Are there competing trials?

- Address study drug, if applicable
  - File for FDA Investigational New Drug (IND) or an IND Exemption
  - Who will supply and who will maintain/administer the drug?
Basic Statistical Concepts for Clinical Trials

James Moon, M.S.
SWOG Statistical Center
At FHCRC, Seattle, Washington
- Randomized designs
- Secondary Objectives (e.g. Technology, Medicine components)
- Pitfalls to avoid
- Time to Event Outcome
- Randomized designs
- Secondary Objectives
- Medicine components
- Pitfalls to avoid
<table>
<thead>
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Phase II Clinical Trial Design for Radiation Oncology

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Presented at OHSU Clinical Trials Course
Date and Time: Friday May 5, 2016 9:00-9:45am
Location: Portland, OR
Introduction and Context

- Overall goals of phase II trials
  - Identify promising therapeutic strategies for subsequent testing in phase III
    - Important to note that endpoints should therefore be similar in phase II and III when evaluating a given treatment approach
  - If phase II trials are successful- phase III trials would favor experimental arm majority of time
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