

**Phase II study of Stereotactic Radiosurgery / Stereotactic Body Radiation Therapy for
patients with oligo-recurrent disease (UPCI# 10-028)
Version dated 11/20/12**

Study Chairs

Study Co-PI:

Steven Burton, MD
Associate Professor
Department of Radiation Oncology
UPMC Presbyterian Shadyside
burtons@upmc.edu
Ph (412) 623-6720
Fax (412) 623-6192

Dwight E. Heron, MD, FACRO, FACR
Professor & Vice Chairman
Department of Radiation Oncology
University of Pittsburgh Cancer Institute
5230 Centre Avenue
Pittsburgh, PA 15232
HeronD2@upmc.edu
Ph. (412) 623 6720
Fax (412) 623-6192

Ray Wynn, MD, FACRO
Clinical Professor
Erie Regional Cancer Center
wynnr@upmc.edu

Andrew Figura, MD
Erie Regional Cancer Center
afigura@trcc.org

Study Co-Chairs:

Michael Gibson, M.D.
Hematology / Oncology
5th Floor, (554) UPMC Cancer Pavilion
5150 Centre Avenue
Pittsburgh, PA 15232

James Ohr, D.O..
UPMC Cancer Pavilion
5150 Centre Avenue
Pittsburgh, PA 15232

Nathan Bahary, MD
UPMC Cancer Pavilion
5150 Centre Avenue, 5th Floor
Pittsburgh, PA 15232
baharyn@upmc.edu

Leonard Appleman, MD
Department of Medical Oncology

Biostatistics:

Hui Xu, MD

xuhuidoc@gmail.com

Study Coordinators:

Karen Holeva (Holevakd@upmc.edu)

Julie Ward, RN, BSN (Wardj@upmc.edu)

Summary

Title: Phase II study of Stereotactic Radiosurgery (SRS) / Stereotactic Body Radiation Therapy (SBRT) for patients with oligorecurrent disease

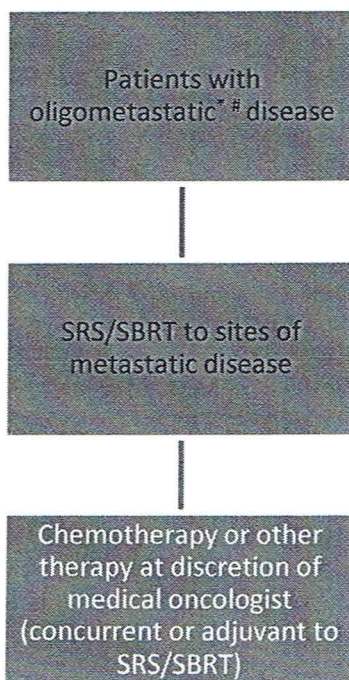
Hypothesis: Patients with limited disease recurrence, known as oligometastatic or oligorecurrent disease (defined here as 5 or fewer sites of metastatic disease) will benefit in terms of overall survival and disease progression from reduced tumor burden and improved local control via radiation to oligometastatic sites.

Primary objective: Phase II study to evaluate feasibility of stereotactic body radiation (SRS) /stereotactic body radiation therapy (SBRT) in patients with oligometastatic disease

Secondary objectives

1. Toxicity (as measured by common toxicity criteria version 3)
2. Quality of life surveys (as measured by FACT quality of life studies)
3. Local control of metastatic sites
4. Overall survival
5. Analysis of patterns of failure post-SRS/SBRT

SCHEMA



* Oligometastatic disease defined as 5 or fewer sites of metastatic disease

Patients may have had previous treatments and recurrent disease, patients with oligometastatic disease at time of initial presentation are eligible for UPMC “Phase II study for curative intent treatment for patients with oligometastatic disease at initial presentation.”

Patient Population: (See Section 3.0 for Eligibility)

Patients with stage IV (M1) disease who have 5 or fewer sites of metastatic disease. Patients can have had previous treatments (surgery, chemotherapy, radiation).

Required Sample Size: 100 patients (See section 11.0)