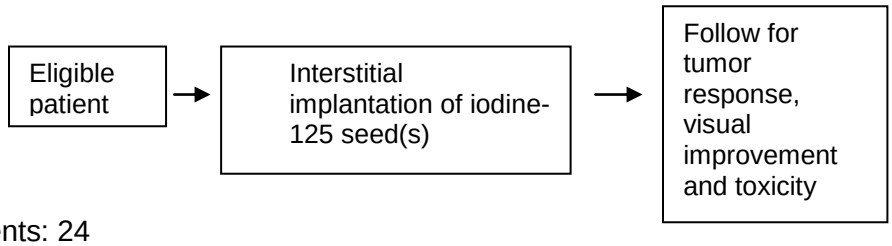
Interstitial Radioactive Iodine Implants for the Treatment of Pan-invasive Pituitary Macroadenomas

1 Schema



Number of patients: 24

2 Objectives

2.1 Primary Objective

2.1.1 To determine if placement of interstitial radioactive iodine seeds for the treatment of pituitary macroadenomas can lead to a partial response (reduction in 30% of tumor volume) or greater response within 12 months from the implant procedure.

2.2 Secondary objectives

2.1.2 To determine if treatment results in a change of the patient's Humphrey visual field testing
2.1.2.1 Timeframe of assessment is up to 5 years post therapy

2.1.3 To assess for potential toxicities associated with interstitial seed placement
2.1.3.1 Specific toxicities that will be monitored are cerebrospinal fluid rhinorrhea, radiation-induced necrosis, changes in visual field deficits, changes in visual acuity, changes in auditory acuity, worsening headaches, and development of neurocognitive and/or short-term memory deficits
2.1.3.2 Timeframe of assessment is up to 5 years post therapy

2.1.4 To determine the progression free survival
2.1.4.1 Timeframe of assessment is up to 5 years post therapy

2.1.5 To determine the effect of the treatment on quality of life evaluations (patient reported outcomes)
2.1.5.1 Timeframe of assessment is up to 5 years post therapy

2.1.6 To evaluate the cost-utility of the treatment arm (in terms of the primary outcome) in comparison with other widely accepted cancer and non-cancer therapies
2.1.6.1 Timeframe of assessment is up to 5 years post therapy

3 Patient Selection

3.1 Conditions for patient eligibility

3.1.1 Pathological or radiographic diagnosis of a pan-invasive pituitary macroadenoma
3.1.2 Pan-invasive for the purposes of the protocol will be defined as meeting each of the following 2 major criteria: 1. tumor volume greater than 20 cc at enrollment, and 2. suprasellar extension. In addition, a pan-invasive tumor must meet any one of the following 3 minor criteria, a) unresectable tumor invasion into a cavernous sinus, b) bone or bone marrow invasion into the clivus or temporal bones, or c) tumor extension in any direction unlikely to be completely removed by specifically a transphenoidal surgical approach.
3.1.3 Patients who meet the two major criteria above (1 and 2) and are medically inoperable for tumor resection (due to confounding co-existing medical problems) are eligible without meeting any of the three minor criteria (a, b, or c).

3.1.4 Patients should be immediately threatened for vision loss or other significant neurological impairment directly related to tumor mass effect. As such, all patients enrolled would likely benefit from tumor response (shrinkage).

3.1.5 Patients must have visible tumor on imaging studies (MRI or CT)

3.1.6 The patient's Zubrod performance status must be 0-3.

3.1.7 Patients must be at least 18 years of age.

3.1.8 Mandatory Imaging Studies: Must be done 45 or fewer days prior to study entry

3.1.8.1 MRI or CT scan of the brain including the entire skull base and all areas of tumor extension

3.2 Conditions for patient ineligibility

3.2.1 Patients who are unable to undergo general anesthesia

3.2.2 Patients who are unable to undergo placement of a stereotactic head frame

3.2.3 Patients who are unable to provide informed consent

3.2.4 Patients who are pregnant or nursing

3.2.5 Patients with severe kidney dysfunction

3.2.6 Patients who have contraindications to MRI, such as implanted pacemaker device

3.2.7 Patients with diagnosis of pituitary carcinoma

4 Study Flow Chart

	Pre-Entry	Months Following Treatment													
		1	3	6	9	12	15	18	21	24	30	36	42	48	Every 12 months for years 4-10
History and Physical Exam	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
MRI Brain	X		X	X	X	X	X	X	X	X	X	X	X	X	X
Weight	X			X					X	X	X	X	X	X	X
Humphrey Visual Field Test	X			X		X		X		X		X		X	X
Visual Acuity	X			X		X		X		X		X		X	X
Audiometry	X			X		X		X		X		X		X	X
Pregnancy test (if applicable)	X														
Endocrinological Evaluation	X					X				X		X		X	X
Creatinine, CBC, platelets, PT/INR, PTT, Serum Chemistry	X														
Neurocognitive Assessment	X					X				X		X		X	X
Blood Draw for Translational Research	X														
Informed consent	X														
QOL Assessment	X			X		X				X		X		X	X
Adverse event evaluation		X	X	X	X	X	X	X	X	X	X	X	X	X	X