Image-guided Cryoablation of Head, Neck and Spine Tumors

NCT02085941

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Study Protocol

Brief Summary:
This research study is evaluating a procedure called cryoablation (the removal of diseased tissue using extreme freezing temperatures) as a possible treatment for head, neck and spine tumors.

Detailed Description:

The participant will be assigned to either group 1 for MRI-guided cryoablation or group 2 for PET/CT guided cryoablation. Each participant's placement will be made by a team of radiologists, medical oncologists, surgical oncologists, and radiation oncologists.

After the eligibility screening

Group 1:

The investigators will assess the participant's tumor by Magnetic Resonance Imaging (MRI). This is a safe and standard exam that will show the physician where the participant's tumor is located. MRI scans typically take 60 minutes. The investigator will ask the participant to complete a "Quality of Life" questionnaire.

Following the participant's baseline scan, the physician will schedule the participant's procedure in the Advanced Multimodality Image-Guided Operating (AMIGO) suite. The participant will be placed under general anesthesia for the procedure. A cryoablation needle will be inserted through the skin and into the tumor using MRI guidance. The tip of the cryoablation needle forms an iceball which will be used to ablate the tumor cells.

The physician will be able to see the tumor during the procedure through the MRI scan. The procedure will take about 3 hours, and the participant will be spending approximately 2 hours in the post-treatment anesthesia care unit. The participant will spend the subsequent night in the hospital, and will be discharged the next day.

The investigators will ask that the participant to return 1 month, 3 months and 6 months post procedure. The participant will be asked to complete the Quality of Life questionnaire at the 1, 3 and 6 month follow up visits.

Group 2:

The investigators will assess the participant's tumor by a Positron Emission Tomography (PET) scan and Computerized Tomography (CT). These are safe and standard exams that will show the physician where the participant's tumor is located. PET/CT scans typically take 60 minutes. The investigator will ask the participant to complete a "Quality of Life" questionnaire.

Following the participant's baseline scan, the physician will schedule the participant's procedure in the AMIGO suite. The participant will be placed under general anesthesia for the procedure. A cryoablation needle will be inserted through the skin and into the tumor using PET/CT guidance. The tip of the cryoablation needle forms an iceball which will be used to ablate the tumor cells.

The physician will be able to see the tumor during the procedure through the PET/CT scan. The procedure will take about 3 hours, and the participant will spend approximately 2 hours in the

post-treatment anesthesia care unit. The participant will spend the subsequent night in the hospital, and will be discharged the next day.

The investigators ask that the participant return 1 month, 3 months and 6 months post procedure. The participant will be asked to complete the Quality of Life questionnaire at the 1, 3 and 6 month follow up visits.

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	30 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Image-guided Cryoablation of Head, Neck and Spine Tumors
Study Start Date :	February 2015
Actual Primary Completion Date :	July 2021
Actual Study Completion Date :	July 2021

Arms and Interventions

Arm
Experimental: Image-guided cryoablation +/- biopsy • MRI/PET/CT imaging in the Advanced Multimodality Image Guided Operating (AMIGO) suite used to place cryoablation needle(s) into target lesion (Mean: 3 cryoprobes, Range: 1-10). • MR/PET/CT imaging in the AMIGO suite will monitor two 15-minute freeze cycles separated by a 10 minut thaw period.

Arm

Outcome Measures

Primary Outcome Measures :

1. Number of participants undergoing image-guided cryoablation of a head, neck, or spine tumor with adverse events [Time Frame: One month]

   Assess the number of adverse events from time of procedure to one month post-procedure.

Secondary Outcome Measures :

1. Progression Rates [Time Frame: 2 Years]

   Assess patient's local progression rates with the criteria proposed by the Interventional Radiology Technology Assessment Committee and the International Working Group on Image-Guided Tumor Ablation

2. QOL Assessment [Time Frame: 2 Years]

   Assess quality of life and pain via the patient self report University of Washington Quality of Life Questionnaire (UW-QOL)

3. Pain assessment [Time Frame: 2 years]

   Assess patient's pain localized to the target of cryoablation with a 10-point Visual Analog Scale (VAS).

Eligibility Criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participants must meet the following criteria on screening examination to be eligible to participate in the study:
- Participants must have histologically confirmed malignant tumor that is metastatic or unresectable and for which standard curative or palliative measures do not exist or are no longer effective.
- Participants with malignant locally recurrent and/or metastatic tumors will be eligible for cryoablation. All tumor shapes and sizes will be eligible for ablation.
- Participants must have sustained all available treatment options (radiation, chemotherapy, surgery) as verified by the Dana Farber Cancer Institute's Head and Neck Tumor Board. These cases will be reviewed by a team of medical oncologists, radiologists, radiation oncologists, and surgical oncologists.
- Participants must have an advanced head, neck or spine malignant tumor that would potentially benefit from a minimally invasive procedure.
- Age 18 years or older

  -- Because no dosing or adverse event data are currently available on the use of cryoablation in participants < 18 years of age, children are excluded from this study but will be eligible for future pediatric III trials.
- Life expectancy of greater than 8 weeks in the opinion of the referring clinician.
- Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 (see Appendix A).
- Participants must have normal organ and marrow function as defined below:
  - Leukocytes ≥ 3,000/microliter (mcL)
  - Absolute neutrophil count ≥ 1,500/mcL
  - Platelets ≥ 100,000/microliter (mcL)
  - Total bilirubin within normal institutional limits
  - Aspartate aminotransferase (AST)/Alanine aminotransferase (ALT) ≤ 2.5 X institutional upper limit of normal

    - Creatinine within normal institutional limits or creatinine clearance ≥ 60 mL/min/1.73 m2 for subjects with creatinine levels about institutional normal .
- Cryoablation can be performed near vessels of the head and neck, and if deemed necessary tumor may be displaced using a saline injection (hydro-displacement). Tumor displacement from nerves may be required and will be performed as deemed appropriate to avoid nerve injury.
- The effects of cryoablation on the developing human fetus are unknown. For this reason women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry and for the duration of study participation. Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her treating physician immediately.
- Ability to understand and the willingness to sign a written informed consent document.
- MRI-Guided Cryoablation Criteria-Cohort 1

  -- Participants must have a mass that is well-visualized under MRI. Since positron emission tomography-computed tomography (PET-CT) guidance requires the nuclear medicine department to administer a radionuclide material, the default will be to try to use MRI guidance.
- PET/CT-Guided Cryoablation Criteria-Cohort 2 -- Patients must have a mass that is well visualized under PET/CT. Tumors that are not clearly seen by MRI but showing on PET/CT will be ablated with PET/CT guidance.

Exclusion Criteria:

- Participants who exhibit any of the following conditions at screening will not be eligible for admission into the study.
- Participants with tumors involving the optic chiasm, brain, or spinal cord will not be eligible for participation in this study. Furthermore, tumors that encase any major blood vessel (carotid, jugular, vertebral) will be excluded from the study due to inability to displace these masses.
- Participants who have had chemotherapy or radiotherapy within 4 weeks (6 weeks for nitrosoureas or mitomycin C) prior to entering the study or those who have not recovered from adverse events due to agents administered more than 4 weeks earlier.
- Participants may not be receiving any other study agents.
- Participants with known brain metastases should be excluded from this clinical trial because of their poor prognosis and because they often develop progressive neurologic dysfunction that would confound the evaluation of neurologic and other adverse events.

- History of allergic reactions attributed to compounds of similar chemical or biologic composition to gadolinium contrast agents, if contrast use is anticipated during the procedure.
- Participants with a blood glucose level of > 200mg/dl prior to the baseline study, known ischemic disease, and/or impaired renal function (eGFR < 60ml/min) will not be eligible for this study.
- Uncontrolled intercurrent illness including, but not limited to ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.
- Pregnant women are excluded from this study because gadolinium is a contrast agent with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk of adverse events in nursing infants secondary to treatment of the mother with gadolinium, breastfeeding should be discontinued if the mother is treated with gadolinium.
- MRI-Guided Cryoablation Exclusion Criteria-Cohort 1
- -Pregnant women are excluded from this study because gadolinium is a contrast agent with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk of adverse events in nursing infants secondary to treatment of the mother with gadolinium, breastfeeding should be discontinued if the mother is treated with gadolinium.
- PET/CT-Guided Cryoablation Exclusion Criteria-Cohort 2
    - Based on potential risks of fetal loss, teratogenicity, fetal growth retardation and carcinogenesis, PET/CT is contraindicated in the pregnant patient.
    - Pregnant women are excluded from this study because PET/CT utilizes a radioactive diagnostic agent with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk of adverse events in nursing infants secondary to treatment of the mother with a radionclide, breastfeeding should be discontinued if the mother is treated.

Statistical Analysis Plan

Tumor size at baseline, 1 month post, 3 months post and 6 months post as well as pain on a VAS scale from 1 to 10 at the same time points will be statistically analyzed by the Student's t test analysis for significant reduction ($p<0.05$) comparing MRI guided ablation versus PET-CT guided ablation.