

Clinical Lung Trial Information Sheet and Enrollment Form

*Stereotactic Radiosurgery (SRS) for the Treatment of Primary
Lung Tumors in Dogs*



Statement of Intent:

PetCure Oncology™ is currently recruiting patients for a prospective study evaluating the effectiveness of stereotactic radiosurgery (SRS) for the treatment of primary lung tumors in canine patients.

How to Enroll:

Complete the Enrollment Form below or visit www.PetCureOncology.com/ClinicalTrials. Any additional inquiries may be directed to the Clinical Trials Coordinator, Brandy Banks, at ClinicalTrials@PetCureOncology.com.

Terms of the Study:

PetCure Oncology is interested in better defining the role of SRS for the treatment of canine patients with primary lung tumors. While this form of therapy is already being used to treat veterinary patients with lung cancer, there are no controlled, prospective studies in the veterinary literature that are designed to truly define the risks and benefits of this kind of radiation therapy for tumors of the canine lung. In order to facilitate case accrual in an appropriate manner, PetCure Oncology will:

1. Provide an SRS video consult free of charge
2. Provide a subsidy of up to \$5,250 towards SRS/SRT treatment course (varies by center)
3. Provide the two-week checkup free of charge
4. Provide the 3- and 12-month follow-up CT free of charge

Eligibility Criteria:

Any canine patient diagnosed with a primary lung tumor is potentially eligible for study entry provided they meet all of the following requirements:

1. Histologic or cytologic confirmation of malignancy is desired, but this requirement may be waived for patients with central/inaccessible tumor locations
2. Complete reference lab bloodwork must be available and less than two weeks old
3. A diagnostic CT scan of the thorax must be performed prior to patient enrollment. Evidence of any metastatic disease is exclusionary for this study, but alternative treatment paths may be available.
4. Significant, life threatening co-morbidities are exclusionary
5. Caregivers must sign informed consent that they understand this is an ongoing clinical study to better define the role of SRS in the treatment of primary lung tumors in dogs
6. Caregivers must agree to follow the prescribed follow-up procedure, including repeat CT scans at 3 and 12 months post-treatment and an autopsy at PetCure's expense for any patient that dies following enrollment in the study

Background and Rationale:

Radiation therapy uses high-energy radiation to shrink tumors and kill cancer cells. The radiation is intended to damage the DNA of the cancer cells beyond repair so that they stop dividing or die. Stereotactic radiosurgery (SRS) is an advanced form of radiation therapy that delivers high-dose radiation with sub-millimeter precision, enabling precise targeting of a tumor with minimal collateral damage to nearby healthy tissue.

SRS has been used to successfully treat both operable and inoperable lung tumors in people.¹⁻⁷ Studies have revealed that SRS is well-tolerated, results in minimal complications and toxicities, maintains or improves quality of life, and results in equivalent survival times when compared to surgery for people with operable tumors.^{1-4,6} Additionally, the peri-procedural morbidity and mortality rate is less for the SRS-treated patients than for those treated surgically.

Hypothesis:

Canine patients with primary lung tumors can be safely and effectively treated with image-guided SRS.

Study Design:

This is a single-arm prospective study. Eligible patients will be treated with a metric-driven protocol consistent with the quality assurance practices of PetCure Oncology and the PetCure Scientific Advisory Board. The protocol has been developed with the guidance of the Scientific Advisory Board.

Contact Information:

If you have questions about enrollment criteria or would like to refer a patient for evaluation/inclusion in the study, contact:

Brandy Banks, R.T. (R)(T)

Radiation Therapist

Clinical Trials Coordinator, PetCure Oncology

ClinicalTrials@PetCureOncology.com

844.308.2578

If you have questions about the study design or the protocol for treatment, contact:

Dr. Neal Mauldin

Dipl. ACVIM (Internal Medicine and Oncology)

Dipl. ACVR (Radiation Oncology)

Director, PetCure Scientific Advisory Board

SAB@PetCureOncology.com

773.850.3400

References:

1. Ematsu MIU, Hioda AKS, Uda ATS, et al. COMPUTED TOMOGRAPHY-GUIDED FRAMELESS STEREOTACTIC RADIOTHERAPY FOR STAGE I NON – SMALL-CELL LUNG CANCER : A 5-YEAR EXPERIENCE. 2001;51(3):666-670.
2. Crabtree TD, Denlinger CE, Meyers BF, et al. Stereotactic body radiation therapy versus surgical resection for stage I non-small cell lung cancer. J Thorac Cardiovasc Surg. 2010;140(2):377-386. doi:10.1016/j.jtcvs.2009.12.054.
3. Collins BT, Vahdat S, Erickson K, et al. Radical cyberknife radiosurgery with tumor tracking: an effective treatment for inoperable small peripheral stage I non-small cell lung cancer. J Hematol Oncol. 2009;2:1. doi:10.1186/1756-8722-2-1.
4. Onishi H, Shirato H, Nagata Y, et al. Stereotactic body radiotherapy (SBRT) for operable Stage I non-small-cell lung cancer: Can SBRT be comparable to surgery? Int J Radiat Oncol Biol Phys. 2011;81(5):1352-1358. doi:10.1016/j.ijrobp.2009.07.1751.
5. Muacevic a, Drexler C, Wowra B, et al. Technical description, phantom accuracy, and clinical feasibility for single-session lung radiosurgery using robotic image-guided real-time respiratory tumor tracking. Technol Cancer Res Treat. 2007;6(4):321-328.
6. Hof H, Herfarth KK, Mütner M, et al. Stereotactic single-dose radiotherapy of stage I non-small-cell lung cancer (NSCLC). Int J Radiat Oncol. 2003;56(2):335-341. doi:10.1016/S0360-3016(02)04504-2.
7. Cancer CL. Image-Guided Radiation Therapy for Non-small. 2008;D(50):177-186.

Veterinary Clinical Lung Trial Enrollment Form

Veterinarian Information

Veterinarian name:

Veterinarian phone number:

Veterinarian email address:

Are you a primary care or specialist veterinarian?

PRIMARY ☐ SPECIALIST ☐

Practice name:

Practice address:

Practice address 2:

City:

State/Province:

Zip/Postal Code:

Country:

Client Information

Patient name:

Breed:

Date of birth:

Gender:

MALE ☐ FEMALE ☐

Client name:

Client phone number:

Client email address:

Questions About your Patient's Diagnosis

Has the patient been diagnosed with primary lung tumor?

YES ☐ NO ☐

NO ☐
*but a primary lung tumor
is strongly suspected*

Does the patient have reference lab bloodwork that is less than two weeks old?

YES ☐ NO ☐

Has the patient had a diagnostic CT scan or three-view metastatic check of the thorax?

YES ☐ NO ☐

*We will contact you to
acquire imaging*

Does the patient have any co-morbidities?

YES ☐ NO ☐

If yes, please describe co-morbidities below:
