

VRTOG Meeting Minutes, VCS conference 2010

Date: October 30, 2010

Time: 7 a.m. – 8 a.m.

Location: Sovereign Room, Loews Coronado Bay Resort and Spa, San Diego CA

In Attendance: Siobhan Haney, Dave Ruslander, Pamela Jones, Eric Boshoven, Elias Gumpel, Nancy Gustafson, Koichi Nagata, Jen Arthur, Janean Fidel, Lisa DiBernardi, Genevieve Hammond, Keijivo Shiomitsu, Dave Proulx, Tracy Geiger, Sheri Siegel, Jamie Curtis, Rodney Ayl, David Lurie (member at large), Michelle Turek (deputy chair), Deb Prescott (chair), Mary K Klein (RO president); others who did not sign in may have been present

Member-at-large Nominations

Deb Prescott called for nominations or volunteers for the vacant member-at-large position in the 2011 VRTOG executive committee. There were no nominations or volunteers. An electronic ballot will be sent via the listserv to elect either Jessica Lawrence or John Farrelly, who volunteered at the ACVR meeting in August.

VRTOG Membership Dues

Deb Prescott sent a membership dues notice to all RO diplomates via the listserv in October. To date, eight institutions have paid the annual \$100 institutional membership fee. She will send the membership dues notice again (via the listserv) after this meeting to ensure that it is received by all. Deb advised that members should ensure that their email address is current on the ACVR website. She encouraged all those who are interested to participate in VRTOG trials to pay the dues. Membership is required for trial participation. The dues are per institution, not per member.

Coarse Fraction RT + Merial Melanoma Vaccine Study

Michelle Turek advised that Merial has declined to fund this VRTOG initiative. Consequently, we will run two concurrent prospective arms: RT + vaccine and RT alone. It will be a non-randomized trial, and the decision for vaccination will be the owners'. The study criteria and data collection sheets will be posted on the VRTOG website.

Concurrently with these prospective studies, we will proceed with the previously planned retrospective study to evaluate '8 Gy X 4 weekly fractions' protocol for canine oral melanoma. Data collection sheets will be posted on the VRTOG website.

RT + Palladia: Feline SCC and Canine Nasosinal Carcinoma

MK Klein announced that she has been able to secure industry support from Pfizer for these two trials. Pfizer will provide Palladia at no cost for both studies, and will provide approximately \$196,000.00 for the nasosinal carcinoma study. These are unrestricted grants. Thus, Pfizer will have no influence on how the studies are performed. The trials may be amended if needed. Both studies were reviewed by the Pfizer PACE group which includes Cheryl London, David Vail and others. Overviews of the studies are outlined below:

Feline SCC: 6 Gy X 6 biweekly fractions and Palladia:

- Cats with oral SCC without lymph node or distant metastasis will be enrolled. Cats may have macroscopic or microscopic disease to qualify. Cats with other health-compromising diseases should not be considered.
- RT prescription will be 6 Gy X 6 fractions over 3 weeks (2 fractions/week). Palladia will be started concurrently with radiotherapy.
- Palladia will be provided at no cost until patient death. Pfizer will distribute the drug directly to the investigator at each institution. Drug can be ordered by the investigator via the telephone. Details about who to contact at Pfizer will be forthcoming.
- Starting dose of Palladia will be 3-3.25 mg/kg. Dose reductions will be allowed. Weight limitations will exist because Palladia exists only in 10 and 15 mg strengths.
- MK Klein will distribute a case-study binder to each institution. Binders contain all enrollment information and documentation required for the study including an owner consent form and data collection sheets. Each cat enrolled in the study will be assigned a binder. Investigators are requested to make copies of the original binder for use with subsequent patients.
- Data should be submitted to MK Klein as it is accrued.
- Tumors will be measured with calipers. This and other details are outlined in the study binder.

MK has treated one cat with this combination protocol. The cat experienced a complete response. It is too soon to comment on durability of the response.

Nasosinal Carcinoma: 4.2 Gy X 10 daily fractions and Palladia:

- Pfizer is funding this study with a \$196,000 grant issued to the VRTOG. The funds will be held in the VRTOG account within ACVR. Like the feline SCC study, this is an unrestricted grant.
- Dogs with histologically confirmed nasal carcinoma without extension beyond the cribriform plate and without lymph node or distant metastasis qualify for enrollment. All carcinomas (adenocarcinoma, SCC, TCC) qualify. Dogs must be fully staged including a pre-treatment CT scan of the nasal tumor. Dogs with other health-compromising diseases should not be considered.
- 45 dogs will be enrolled into the RT + Palladia group. As controls, 15 dogs will be treated with Palladia alone. This is a non-randomized study. The decision to pursue radiation is the owners'. Historical controls of radiation alone will be used (Chess Adams and Lisa Forrest's data).
- Owner will pay for diagnostic tests and the pre-treatment/planning CT scan.

- RT prescription will be 4.2 Gy X 10 daily fractions. Palladia will be started concurrently with radiotherapy. Radiation will be at the owner's expense.
- Radiation delivery must be computer planned. DVHs will be submitted by the investigator to MK Klein.
- Palladia will be provided by Pfizer for one year. Pfizer will distribute the drug directly to the investigator at each institution. Drug can be ordered by the investigator via the telephone. Details about who to contact at Pfizer will be forthcoming.
- Palladia starting dose will be 3-3.25 mg/kg EOD. Dose reductions are allowable. Drug holidays of <1 week are allowable.
- Pfizer will provide \$1200 per patient for follow-up CT scans. A CT scan will be performed at three months from starting the Palladia or completion of radiation therapy + Palladia. Tumor response at this time point is the principal endpoint of this study. Serial CT scans are preferred. Institutions are encouraged to obtain as many CT scans as possible with this funding. If additional CT scans are possible, then imaging at the time of suspected treatment failure (progressive disease) is encouraged. If more than 2 CT scans are possible, then imaging is suggested q 3 months. CT images will be collected and reviewed by a single radiologist. Pre- and post-contrast images should be acquired.
- Pfizer will also provide funding for regular rechecks and regular CBCs to ensure adequate monitoring of Palladia. A total of \$3300/dog is available, including \$1200 for CT imaging. The study provides funding for one-year of follow up. Follow-up examinations and tests, including blood work, should be performed by the investigator and not the referring veterinarian.
- Biochemical profiles should be done at the clinician's discretion.
- MK Klein recommends that patients be evaluated monthly while on Palladia.
- Concurrent medications: Anti-diarrhea medication, prednisone and tramadol or other narcotics are allowable. MK Klein recommends starting famotidine for all dogs receiving Palladia. NSAIDs should be avoided as they may confound results. Similarly, herbals, antioxidants, shark cartilage and other nutraceuticals/holistic therapies should also be avoided. The aim is to make the study as non-biased as possible.
- Money will be distributed through ACVR to the investigator at each institution at monthly intervals once the data collection forms from that month have been submitted. The faxed data collection forms will function as invoices. Data forms should be submitted by fax to MK Klein at the fax number on forms as information is collected. MK Klein's resident will oversee and monitor data collection. If problems with distribution of money occur, MK Klein should be contacted.

- Endpoints of this study are tumor response at 90 days post-RT (based on the first funded CT scan), progression free survival and survival time. Maximum VRTOG toxicity will also be evaluated at days 14 and 28.
- At the time of progressive disease, any therapy is allowable.
- MK Klein will distribute a case-study binder to each institution. Binders contain all enrollment information and documentation required for the study including an owner consent form and data collection sheets. Each dog enrolled in the study will be assigned a binder. Investigators are requested to make copies of the original binder for use with subsequent patients. As patients are enrolled, MK Klein will speak to each investigator on the telephone to review the information in the binder and the data collection/submission process.
- Data should be submitted to MK Klein as it is accrued. Money will be distributed progressively as evaluations/testing are performed and data is submitted. Money will not be released until data is received by MK Klein.

Anal Sac Adenocarcinoma Retrospective Study

A retrospective study proposal has been submitted to the executive committee for review.

Thyroid Carcinoma Retrospective Study

A retrospective study proposal will be submitted to the executive committee for review.

VRTOG website

The VRTOG webpage on the ACVR website will be updated. Study information, including data collection sheets for the non-Pfizer studies, and contact information for principle investigators will be available on the site.

Next Meeting

The next VRTOG meetings will be held in October 2011 at the VCS and ACVR conferences. These conferences will take place in Albuquerque within 2 weeks of each other.

End

Prepared by: Michelle Turek