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Interview with Dr Damien Weber about the Atypical and Anaplastic Meningioma Trial

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Q: *Dr Weber, can you tell us about the ongoing "Atypical and Anaplastic Meningioma" trial? What are its rationale and background?*

A: A number of retrospective studies have shown that patient outcome is improved when the radiation dose is escalated for non-benign (ie, WHO grade-II/III) meningiomas. The objective of the EORTC 22042-26042 study is thus to assess the impact of high-dose radiation therapy on progression-free survival.

Q: *How is the trial designed and what are the inclusion criteria?*

A: To be included in the study, patients must be between 18 and 70 years of age with good performance status (WHO 0–2) and present with a tumour of non-benign histology. The meningioma may be located anywhere except in optic nerves. In addition, patients must not have very deteriorated neurological function (NF score 2) and must not have had any prior cancer nor any previous irradiation to the brain. Once in the study, the patient receives the irradiation. The radiation dose (60 vs 70 Gy) is selected as a function of the extension of the tumour resection: 60 Gy for complete resection and otherwise 70 Gy (ie, Simpson 1–3 vs 4–5).

Q: *To my knowledge, this is the first prospective trial in this rare disease. Is that correct?*

A: Absolutely, this trial is the first prospective trial to be initiated in a cooperative research group. It was an endeavour, as the activation of the 22042 trial followed after the failure of a phase-III trial for benign meningioma (EORTC 22021-26021). This trial was stopped due to poor accrual. Later, the Radiation Oncology Group initiated an observational/therapeutic phase-II trial (RTOG 0539). Both prospective trials are accruing well.

Q: *Which groups, countries and how many centres participate in the trial?*

A: Twenty-five sites from 7 countries recruit to the trial: Belgium, France, Spain, Switzerland, the Netherlands, Italy, and United Kingdom.

Q: *Did you have any stratification factors?*

A: No, the study is not randomized but the cohorts and doses are specific to the WHO grade (II vs III) and the extent of the surgery (based on Simpson's classification) as explained.

Q: *Is there a specific quality assurance programme for radiotherapy in the trial?*

A: Quality assurance (QA) will be performed by the Image-Guided Therapy Center – Advanced Technology Consortium (http://atc.wustl.edu/) in the US. Prospective Individual Case Reviews (ICRs) are mandatory for each patient included in this trial. All centres are credentialed by a Dummy Run submission prior to trial activation. This is also the first prospective trial using a QA digital platform, eCRFs, and prospective ICRs.

Q: *Do you have any translational or biological investigation in this trial?*

A: Yes, biological materials are prospectively collected for future research.

Q: *There was an amendment regarding the inclusion criteria during the study. Can you tell us about that?*

A: First, the sample size for Simpson 1–3 WHO grade-II disease has been increased from 25 to 54 patients. Second, we did remove the statistical objectives for the rare group of patients with Simpson 4–5 WHO grade-II disease, which became part of the observational study. Finally, the delay between surgery and the start of radiotherapy is less stringent with the last amendment, but should be kept at less than 6 weeks. However, in exceptional circumstances up to 8 weeks are allowed prior to HQ approval.

Q: *How is the accrual ongoing and when do you expect to reach the accrual goal? When can we expect to see the first results published?*

A: The trial has accrued ¾ of its planned cohort of Simpson 1–3 WHO grade-II patients. First results should be available in 2015.

Thank you very much.

Damien Weber is the study coordinator for the EORTC 22042-26042 trial entitled, "Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a phase-II and observation study."

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