The ROAM / EORTC 1308 trial: Radiation versus observation following surgical resection of atypical meningioma – study update

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Introduction: Atypical meningioma are very rare tumours with a recurrence rate of 30-58% at 5-years. A systematic literature review reported that the role of early adjuvant radiotherapy has not been defined and there have been no randomised controlled trials (RCT). As part of a collaboration between NIHR and EORTC we have establised an international multi-centre RCT to determine whether early radiotherapy reduces tumour recurrence compared to observation following gross total resection of atypical meningioma

Materials and Methods: A total of 190 patients with newly-diagnosed atypical meningioma who have undergone a Simpson I-III resection will be randomised 1:1 between early radiotherapy (60Gy in 30 fractions) & observation. Using an estimate of 40% recurrence for the control group and 20% for the radiotherapy group then a 0.05 level two-sided log-rank test for equality of survival curves with 80% power would require 86 patients in each arm (total number of events required = 46). The primary outcome measure is time to MRI evidence of tumour recurrence (progression free survival (PFS)). Secondary outcome measures including assessing the toxicity of radiotherapy, the quality of life, neurocognitive function, time to second line treatment, time to death (overall survival) and incremental cost per quality-adjusted life year (QALY). Tumour tissue and serum will be collected for translational research. Qualitative researchers will interview patients and clinicians to identify reasons for recruitment difficulties and inform recruitment strategies.

Results: The trial opened in April 2016 and is planned to open in 49 sites across the UK, Europe and Australia. 4 centres are open and 2 patients have been randomised within the main trial. 4 patients have participated in the qualitative interviews. Updated recruitment figures will be presented.

Conclusions: ROAM / 1308 will provide class I evidence of the role of early adjuvant radiotherapy in the managment of atypical meningioma. A unique bank of tissue and blood samples will be available for future translational research.

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