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### **Radiosurgery versus Surgery, both with Adjuvant Whole Brain Radiotherapy, for Solitary Brain Metastases: A Randomised Controlled Trial.**

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#### **Abstract**

**AIMS:** This randomised non-inferiority trial was designed to assess whether radiosurgery plus adjuvant whole brain radiotherapy (RS + WBRT) is as effective as surgery plus whole brain radiotherapy (S + WBRT) for cancer patients with a solitary brain metastasis, with respect to overall survival and quality of life.

**MATERIALS AND METHODS:** Major inclusion criteria were a history of systemic cancer within 5 years and enhanced magnetic resonance imaging-confirmed solitary brain metastasis suitable for both radiosurgery and surgery. All patients were to receive WBRT (30 Gy in 10 fractions). Between February 2003 and April 2009, 40 patients were considered eligible, 22 consented to randomisation and 21 were analysed (11 RS + WBRT, 10 S + WBRT). The trial was closed early due to slow accrual.

**RESULTS:** The estimated median overall survival times for RS + WBRT and S + WBRT patients were 6.2 and 2.8 months, respectively (hazard ratio 0.53, 95% confidence interval 0.20-1.43, P = 0.20). Corresponding median failure-free survival times were 3.1 and 1.7 months (P = 0.20). For 19 'per protocol' patients, 2/10 in the RS + WBRT arm had distant intracranial failure (one also had local failure) and 3/9 S + WBRT patients had distant intracranial failure (no local failures). There were no grade 3-4 late radiation toxicities. Two months after starting treatment there were no significant differences in quality of life between the arms.

**CONCLUSION:** This randomised trial encountered the accrual difficulties and consequent low statistical power commonly associated with interdisciplinary studies drawing from a small eligible population, but can contribute to future overviews on the management of solitary brain metastases.

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