

PubMed

U.S. National Library of Medicine
National Institutes of Health



Display Settings: Abstract

[BMC Cancer](#). 2011 Apr 17;11(1):142. [Epub ahead of print]

Whole brain radiotherapy after local treatment of brain metastases in melanoma patients - a randomised phase III trial.

[Fogarty G](#), [Morton RL](#), [Vardy J](#), [Nowak AK](#), [Mandel C](#), [Forder PM](#), [Hong A](#), [Hruby G](#), [Burmeister B](#), [Shivalingam B](#), [Dhillon H](#), [Thompson JF](#).

Abstract

ABSTRACT: **BACKGROUND:** Cerebral metastases are a common cause of death in patients with melanoma. Systemic drug treatment of these metastases is rarely effective, and where possible surgical resection and/or stereotactic radiosurgery (SRS) are the preferred treatment options. Treatment with adjuvant whole brain radiotherapy (WBRT) following neurosurgery and/or SRS is controversial. Proponents of WBRT report prolongation of intracranial control with reduced neurological events and better palliation. Opponents state melanoma is radioresistant; that WBRT yields no survival benefit and may impair neurocognitive function. These opinions are based largely on studies in other tumour types in which assessment of neurocognitive function has been incomplete. **Methods / Design:** This trial is an international, prospective multi-centre, open-label, phase III randomised controlled trial comparing WBRT to observation following local treatment of intracranial melanoma metastases with surgery and/or SRS. Patients aged 18 years or older with 1-3 brain metastases excised and/or stereotactically irradiated and an ECOG status of 0-2 are eligible. Patients with leptomeningeal disease, or who have had previous WBRT or localised treatment for brain metastases are ineligible. WBRT prescription is at least 30Gy in 10 fractions commenced within 8 weeks of surgery and/or SRS. Randomisation is stratified by the number of cerebral metastases, presence or absence of extracranial disease, treatment centre, sex, radiotherapy dose and patient age. The primary endpoint is the proportion of patients with distant intracranial failure as determined by MRI assessment at 12 months. Secondary end points include: survival, quality of life, performance status and neurocognitive function. **DISCUSSION:** Accrual to previous trials for patients with brain metastases has been difficult, mainly due to referral bias for or against WBRT. This trial should provide the evidence that is currently lacking in treatment decision-making for patients with melanoma brain metastases. The trial is conducted by the Australia and New Zealand Melanoma Trials Group (ANZMTG-study 01-07), and the Trans Tasman Radiation Oncology Group (TROG) but international participation is encouraged. Twelve sites are open to date with 43 patients randomised as of the 31st March 2011. The target accrual is 200 patients. Trial registration: Australia and New Zealand Clinical Trials Registry (ANZCTR) # ACTRN12607000512426.

PMID: 21496312 [PubMed - as supplied by publisher] [Free Article](#)

[LinkOut - more resources](#)