

## PubMed

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



Display Settings:  Abstract

[J Neurooncol.](#) 2010 Jan 10. [Epub ahead of print]

### Phase II trial of intratumoral BCNU injection and radiotherapy on untreated adult malignant glioma.

Jenkinson MD, Smith TS, Haylock B, Husband D, Shenoy A, Vinjamuri S, Walker C, Pietronigro D, Warnke PC.

Department of Neurosurgery, The Walton Centre for Neurology and Neurosurgery, Lower Lane, Liverpool, L9 7LJ, UK, michael.jenkinson@liv.ac.uk.

DTI-015 (BCNU dissolved in ethanol) utilizes solvent facilitated perfusion (SFP) for intratumoral drug delivery. A phase II clinical trial of DTI-015 and fractionated external beam radiotherapy on newly diagnosed, malignant gliomas investigated early changes in tumour physiology and metabolism, clinical outcome and safety. Pre- and post DTI-015 injection neuro-imaging included computed tomography (CT) cerebral blood flow and volume, glucose and thallium single photon emission computed tomography (SPECT) and magnetic resonance imaging (MRI). Clinical status was determined before and after DTI-015, prior to radiotherapy and 3 monthly thereafter until progression (defined by Macdonald criteria). Primary endpoint was radiographic response. Secondary endpoints were progression free (PFS) and overall survival (OS). Twelve patients were enrolled; eight glioblastoma multiforme (GBM), four anaplastic astrocytoma (AA). Three days after DTI-015 injection, mean tumour blood flow (Paired t-test;  $P < 0.001$ ) and blood volume (Paired t-test;  $P = 0.001$ ) were significantly reduced. There was a significant decrease in glucose utilization (Paired t-test;  $P < 0.001$ ) and thallium uptake (Paired t-test;  $P < 0.001$ ) at 6 days. Tumour blood volume had a sustained reduction (Paired t-test;  $P = 0.001$ ) at 26 days after DTI-015. There were two serious adverse events. Two patients with AA achieved a partial response. Median PFS was 39 weeks for AA and 27 weeks for GBM; median OS for GBM was 47 weeks and 132 weeks for AA. The imaging data forms a biological basis for understanding the effects of high dose BCNU delivered intratumorally by SFP, and suggests early effects on tumour vasculature and metabolism.

PMID: 20063175 [PubMed - as supplied by publisher]

[LinkOut - more resources](#)