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Prospective clinical trials of brain tumor therapy: the critical role of neurosurgeons.

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Abstract

Prospective clinical trials are critical to the scientific evaluation of new treatments for brain tumors. This paper reviews basic concepts of early and late phase prospective clinical trials that are most relevant to neurosurgical oncologists, with an emphasis on the challenges associated with conducting clinical trials of brain tumor therapies. Novel clinical trial designs that meet these challenges by incorporating pretreatment 'molecular profiling' and post-treatment 'molecular endpoints' are described. Because of their ability to obtain brain tumor specimens from patients before and after treatment, neurosurgeons have been required to play an increasingly important role in the execution of these molecular-based clinical trials. Potential avenues for enhancing the participation of neurosurgeons in the design and development of clinical trials are discussed.

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