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## Appropriate end-points for right results in the age of antiangiogenic agents: Future options for phase II trials in patients with recurrent glioblastoma.

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### Abstract

The progression-free survival rate at 6 months (PFS-6) has long been considered the best end-point for assessing the efficacy of new agents in phase II trials in patients with recurrent glioblastoma. However, due to the introduction of antiangiogenic agents in this setting, and their intrinsic propensity to alter neuroradiological disease assessment by producing pseudoregression, any end-point based on neuroradiological modifications should be reconsidered. Further, statistically significant effects on progression-free survival (PFS) only should not automatically be considered reliable evidence of meaningful clinical benefit. In this context, because of its direct and unquestionable clinical relevance, overall survival (OS) represents the gold standard end-point for measuring clinical efficacy, despite the disadvantage that it is influenced by subsequent therapies and usually takes longer time to be evaluated. Therefore, while awaiting novel imaging criteria for response evaluation and/or new imaging tools to distinguish between 'true' and 'pseudo'-responses to antiangiogenic agents, the measurement of OS or OS rates should be considered primary end-points, also in phase II trials with these agents.

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