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Efficacy of radioactive hypoxia-targeting therapeutic agent 64Cu-ATSM on recurrent malignant glioma: a study protocol for a phase-III, investigator-sponsored, randomized controlled trial

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Abstract

Previously, we conducted the phase I study of 64Cu-ATSM, which is Cu-diacetyl-bis (N4-methylthiosemicarbazone) radiolabeled with Cu-64, for patients with brain tumors and determined the maximum tolerated dose. We started a subsequent multicenter, randomized, open-label phase III study to evaluate the efficacy of 64Cu-ATSM as an investigator-initiated registration-directed trial for recurrent or residual malignant glioma (protocol No. NCCH2301, STEP-64). Patients will be randomized to either the control or study arm (64Cu-ATSM). A large-scale randomized trial seems difficult to perform for patients with brain tumors because of small sample sizes. Therefore, we designed a small randomized trial with 56 patients. Furthermore, as a pragmatic approach in the control arm, physicians can choose treatments depending on the patient's condition among the clinically available options, where the drugs used are not regarded as investigational. The trial was registered in the Japan Registry of Clinical Trials as jRCT2031240090.

Keywords: 64Cu-ATSM; glioma; randomized controlled trial.