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# Protocol for a pilot-randomized trial in newly diagnosed glioblastoma: standard care with or without daily intranasal perillyl alcohol

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## Abstract

Glioblastoma (GB) is a highly malignant brain tumor with poor prognosis and limited treatment options. Standard treatment, surgery followed by chemoradiation with temozolomide (TMZ), yields an average survival of 18 months. Preclinical studies indicate that perillyl alcohol (POH) is cytotoxic to TMZ-sensitive and -resistant cells and acts as a radiosensitizer. Clinical studies of intranasal POH show low toxicity and potential survival benefits in recurrent gliomas. This study aims to evaluate the effects of POH alongside standard treatment in newly diagnosed GB patients. Eligible patients at the Oncology Services of the University of Campinas General Hospital and Municipal Hospital Mário Gatti will be assigned to a control group (chemoradiation) or an intervention group (chemoradiation + POH). Follow-up will occur every 4 months for 1 year. The primary outcome is progression-free survival, with secondary outcomes including overall survival, blood levels of *P*-selectin and von Willebrand factor, and tumor response assessed by cranial MRI. Previous studies have reported positive effects of intranasal POH in patients with recurrent gliomas. This study evaluates an adjunct protocol combining intranasal POH with standard therapy in newly diagnosed GB patients. This randomized clinical trial aims to support future research and guide clinical practice. **Clinical trial registration:** RBR-4ngc9n5 ([www.ensaiosclinicos.gov.br](http://www.ensaiosclinicos.gov.br)).

**Keywords:** Glioblastoma; chemoradiation; intranasal; perillyl alcohol; treatment.

## Plain language summary

Glioblastoma is an aggressive type of brain tumor that is very hard to treat, and people diagnosed with this tumor usually have a short-life expectancy. The standard treatment includes surgery followed by chemotherapy and radiotherapy, but this treatment only extends survival to about 18 months on average. Recent research suggests that a natural compound called perillyl alcohol may help fight glioblastoma. Studies in the lab show that perillyl alcohol can kill tumor cells and make them more sensitive to radiotherapy. Early clinical studies using perillyl alcohol through the nose have shown this is safe and may help patients with recurring tumors live longer. This study will test whether adding intranasal perillyl alcohol to the usual treatment can help patients newly diagnosed with glioblastoma. Patients at two hospitals in Campinas, Brazil, will receive either the standard treatment or standard

treatment plus perillyl alcohol. This study will follow patients for a year, checking tumor growth, overall survival, and certain blood markers. The goal of this research is to see if combining perillyl alcohol with standard therapy can improve outcomes and help guide future treatments for glioblastoma.

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