J Clin Oncol. 2006 Aug 1;24(22):3644-50.

Phase I single-dose study of intracavitary-administered iodine-131-TM-601 in adults with recurrent high-grade glioma.

Mamelak AN[1], Rosenfeld S, Bucholz R, Raubitschek A, Nabors LB, Fiveash JB, Shen S, Khazaeli MB, Colcher D, Liu A, Osman M, Guthrie B, Schade-Bijur S, Hablitz DM, Alvarez VL, Gonda MA.

Author information

1 Maxine Dunitz Neurosurgical Institute, Cedars Sinai Medical Center, Los Angeles, CA 90048, USA. Adam.Mamelak@cshs.org

Abstract

PURPOSE: TM-601 binds to malignant brain tumor cells with high affinity and does not seem to bind to normal brain tissue. Preclinical studies suggest that iodine-131 (131I) - TM-601 may be an effective targeted therapy for the treatment of glioma. We evaluated the safety, biodistribution, and dosimetry of intracavitary-administered 131I-TM-601 in patients with recurrent glioma.

PATIENTS AND METHODS: Eighteen adult patients (17 with glioblastoma multiforme and one with anaplastic astrocytoma) with histologically documented recurrent glioma and a Karnofsky performance status of > or = 60% who were eligible for cytoreductive craniotomy were enrolled. An intracavitary catheter with subcutaneous reservoir was placed in the tumor cavity during surgery. Two weeks after surgery, patients received a single dose of 131I-TM-601 from one of three dosing panels (0.25, 0.50, or 1.0 mg of TM-601), each labeled with 10 mCi of 131I.

RESULTS: Intracavitary administration was well tolerated, with no dose-limiting toxicities observed. 131I-TM-601 bound to the tumor periphery and demonstrated long-term retention at the tumor with minimal uptake in any other organ system. Nonbound peptide was eliminated from the body within 24 to 48 hours. Only minor adverse events were reported during the 22 days after administration. At day 180, four patients had radiographic stable disease, and one had a partial response. Two of these patients further improved and were without evidence of disease for more than 30 months.

CONCLUSION: A single dose of 10 mCi 131I-TM-601 was well tolerated for 0.25 to 1.0 mg TM-601 and may have an antitumoral effect. Dosimetry and biodistribution from this first trial suggest that phase II studies of 131I-TM-601 are indicated.

PMID: 16877732 DOI: 10.1200/JCO.2005.05.4569

[Indexed for MEDLINE]

Publication types, MeSH terms, Substances

LinkOut - more resources

PubChem Compound (MeSH Keyword)

Taxonomy via GenBank

Protein

Cited in PMC

Cited in Books

Recent Activity

Turn Off Clear

Phase I single-dose study of intracavitary- PubMed

Uptake and gene expression with antitu PubMed

uptake and antitumoral effects of iodine and PubMed

Recurrent Aphthous Stomatitis

Recurrent aphthous stomatitis. PubMed

See more...