



Fondation du Centre
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

ZOOM NOVOCURE

Indication	Glioblastome, adjuvant
Title	A Prospective, Multi-center Trial of NovoTTF-100A Together With Temozolomide Compared to Temozolomide Alone in Patients with Newly Diagnosed GBM
Protocol ID	Novocure – EF-14
Phase	Phase III
Sponsor	NovoCure Ltd., Israel
Local Principal Investigator	Dr R. Stupp
Primary Objective	To compare the efficacy and safety outcome of newly diagnosed GBM patients treated with NovoTTF-100A concomitant to Temozolomide to those treated with Temozolomide alone
Inclusion/exclusion criteria	<p>Inclusion Criteria include the following :</p> <ul style="list-style-type: none"> • Pathological evidence of GBM using WHO classification criteria. • ≥ 18 years of age. • Received maximal debulking surgery and radiotherapy with Temozolomide. • Karnofsky scale ≥ 70 • Life expectancy at least 3 months • Participants of childbearing age must use effective contraception. • All patients must sign written informed consent. • Treatment start date at least 4 weeks out from surgery. • Treatment start date at least 4 weeks out but not more than 7 weeks from last dose of adjuvant Temozolomide. • Treatment start date at least 4 weeks out from radiation therapy. <p>Exclusion Criteria include the following:</p> <ul style="list-style-type: none"> • Progressive disease (according to MacDonald Criteria). • Actively participating in another clinical treatment trial • Pregnant • Significant co-morbidities at baseline which would prevent maintenance Temozolomide treatment:

	<ol style="list-style-type: none">1. Thrombocytopenia (platelet count < 100 x 10³/μL)2. Neutropenia (absolute neutrophil count < 1.5 x 10³/μL)3. CTC grade 4 non-hematological Toxicity (except for alopecia, nausea, vomiting)4. Significant liver function impairment - AST or ALT > 3 times the upper limit of normal5. Total bilirubin > upper limit of normal6. Significant renal impairment (serum creatinine > 1.7 mg/dL) <ul style="list-style-type: none">• Implanted pacemaker, defibrillator or deep brain stimulator, or documented clinically significant arrhythmias.• Infra-tentorial tumor• Evidence of increased intracranial pressure (midline shift > 5mm, clinically)• significant papilledema, vomiting and nausea or reduced level of consciousness)• History of hypersensitivity reaction to Temozolomide or a history of hypersensitivity to DTIC.
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