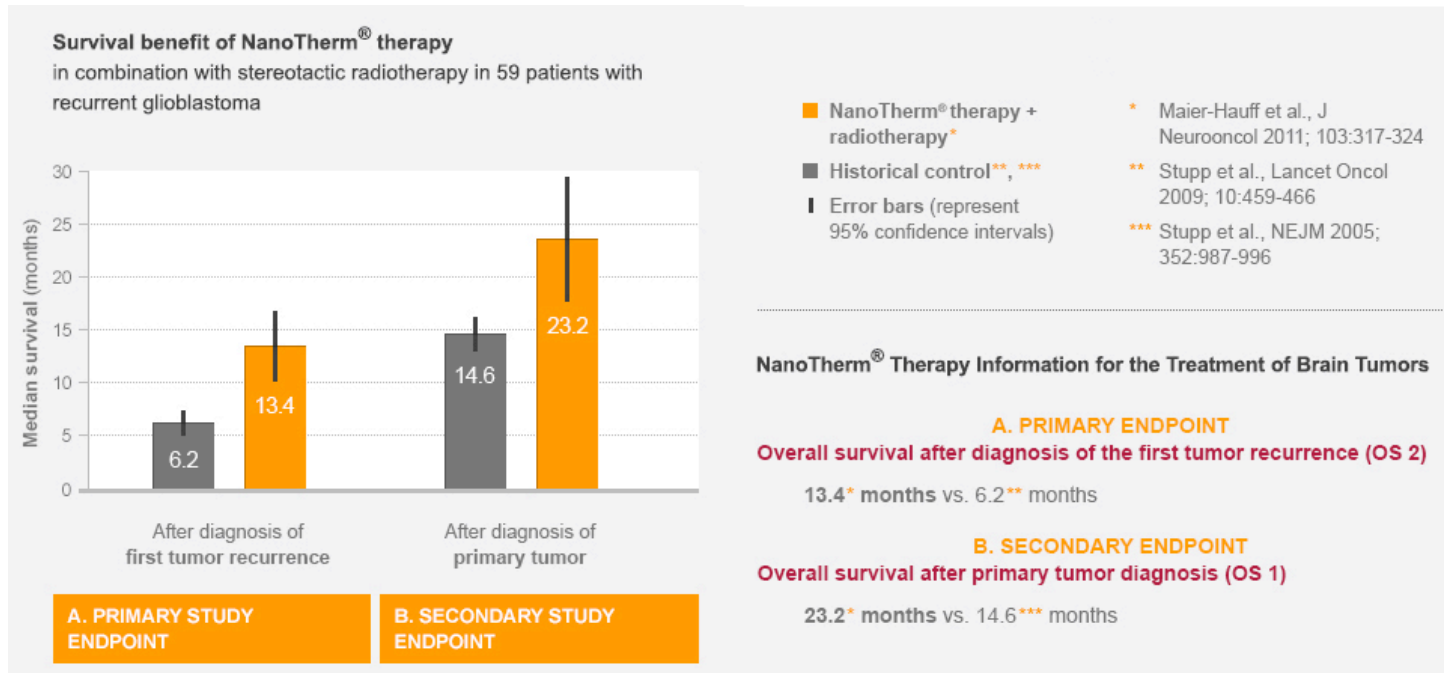


NanoTherm® Therapy Information for the Treatment of Brain Tumors

NanoTherm® therapy is an intratumoral thermotherapy which aims to help patients with brain tumors. It can be used as a monotherapy or in combination with radiotherapy and/or chemotherapy to enhance their effectiveness.



With NanoTherm® therapy, superparamagnetic iron oxide nanoparticles (NanoTherm®) are injected into a tumor and heated up by an alternating magnetic field, generated by the NanoActivator®. The heat either destroys the tumor cells or sensitizes them for additional therapies such as radiotherapy and/or chemotherapy. Thus, their efficacy is improved.

NanoTherm® Therapy was clinically investigated in approximately 90 patients with brain tumors and about 80 patients with other tumors such as pancreatic, prostate or esophageal cancer.

NanoTherm®, NanoPlan®, and NanoActivator® are components of NanoTherm® therapy and are CE marked as medical devices according to directive 93/42/EEC.

Results from the glioblastoma study, the basis of the approval of the NanoTherm® therapy, showed a median overall survival (mOS 2) of 13.4 months from diagnosis of the first tumor recurrence for patients with one or more recurrences of this brain tumor, who were treated with NanoTherm® therapy in combination with external beam radiotherapy. For the mOS 1 from diagnosis of the primary tumor, 23.2 months were achieved with NanoTherm® therapy and radiation treatment. Thus, NanoTherm® therapy in combination with radiotherapy yielded good benefit for glioblastoma patients.

COURSE OF TREATMENT OF NANOTHERM® THERAPY

The therapy is administered as follows:

REMOVAL OF METALS NEAR THE BRAIN TUMOR

Metallic materials within approximately 55 cm from the brain tumor must be removed or replaced because all metallic material will heat up during NanoTherm® therapy. Typically, titanium clamps/clips, metallic teeth fillings, crowns and implants are to be removed. Patients with irremovable cardiac pacemaker, defibrillator, neurostimulators, shoulder joint replacements or other metallic or electronic implants cannot be treated. MagForce Patient Services can support patients in case dental rework is required.



INTRODUCTION OF THE NANOPARTICLES INTO THE TUMOR

In order to plan the NanoTherm® therapy, imaging of the brain by Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) or Computed Tomography (CT) is mandatory. This imaging data is used to determine the location, size, and shape of the tumor and, derived from that, the dosage and position/s for the injection/s of the NanoTherm® nanoparticles into the tumor. A minimally invasive surgical procedure, e.g. burr hole trepanation, followed by stereotactic or neuronavigational injection is used to instill the magnetic fluid into the tumor. A thermometry catheter is placed in the nanoparticle deposits in the treatment area to allow direct temperature measurement during thermotherapy.



THERMOTHERAPY IN THE NANOACTIVATOR®

The NanoActivator® is a medical device that was specifically developed for NanoTherm® therapy. It generates a homogenous alternating magnetic field which changes its polarity 100,000 times per second and which is tailored to heat the NanoTherm® nanoparticles. For treatment, the patient is positioned on the NanoActivator® patient stretcher in the opening to ensure that the treatment area is located in and completely covered by the magnetic field.

NanoTherm® Therapy is currently available at selected clinical centers in Germany.

TREATMENT SIDE EFFECTS

During and/or after treatment in the NanoActivator®, the primary side effects reported were sweating, feeling hot generally and in the treatment area, a slight increase in body temperature, an accelerated pulse rate (tachycardia), headaches or high blood pressure. Seizures and motor disturbances were observed in some patients, however in most cases, the events were preexisting and only in a few cases they occurred for the first time. In addition, in a small number of patients a rise in body temperature to more than 38°C and lowered blood pressure (hypotension) were observed. No hypersensitive or allergic reactions were observed in the clinical studies to date.

CONTACT

To assess if NanoTherm® therapy can be beneficial in your particular medical situation please call our toll free number from the following countries:

Austria, Czech Republic, France, Germany, Italy, Poland, Spain, Switzerland, Turkey, and UK:

+800-MAGFORCE (+800-62 43 67 23)

from the United States, Canada, Guam, Puerto Rico, and US Virgin Islands:

+1-844-833-9623

or direct dial for English support:

+49 30 – 30 83 80 – 73

You can also send us an email at patient-info@magforce.com and the MagForce Patient Service will send you additional personalized information and explain how NanoTherm® therapy can be applied in your particular case.

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