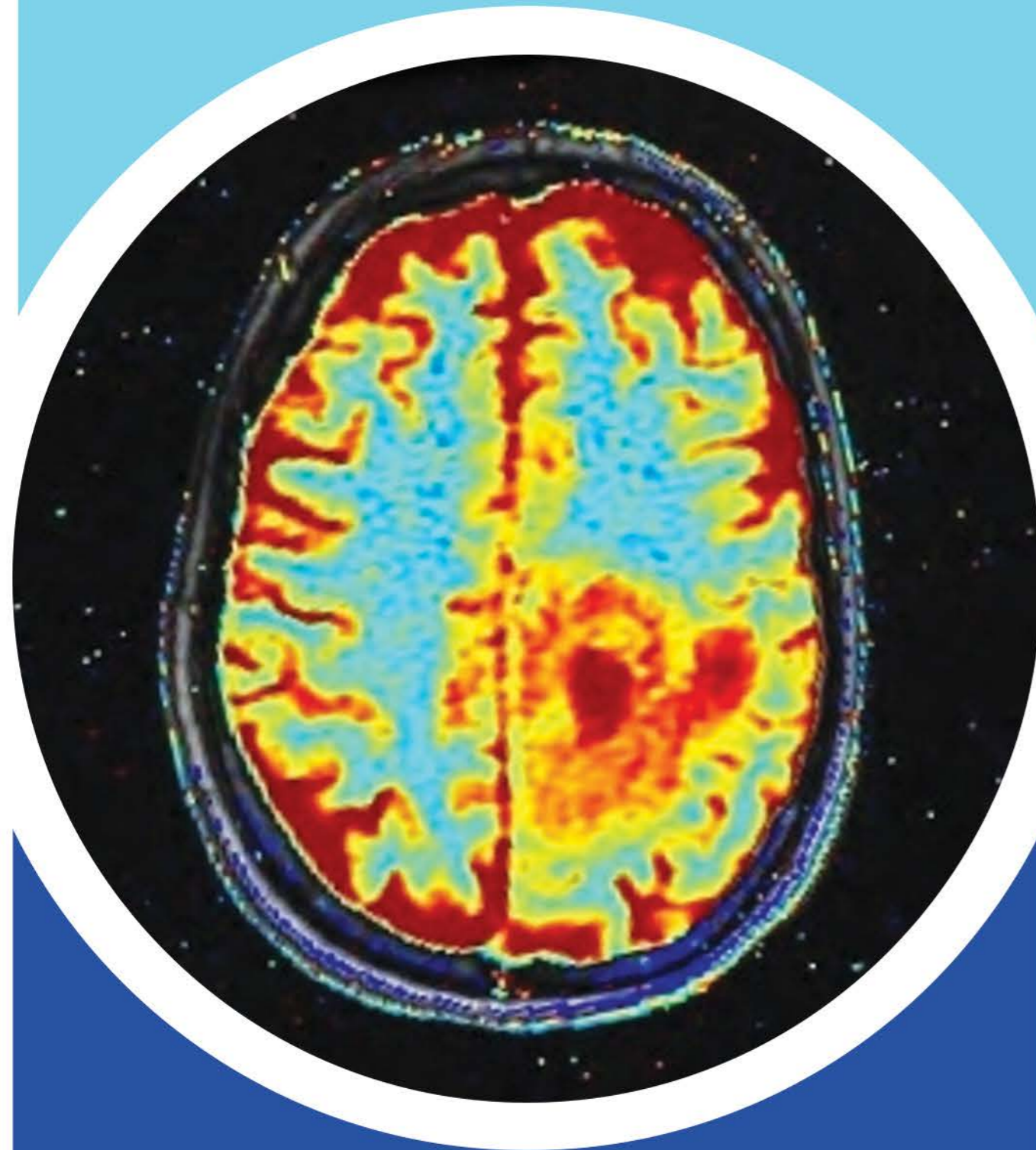




Glioblastoma

THE RESTORE STUDY



NanoO₂TM

Phase II Clinical Trial

A DOUBLE-BLIND, RANDOMIZED, STUDY OF NANO₂TM IN NEWLY DIAGNOSED GLIOBLASTOMA MULTIFORME PATIENTS

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Standard Glioblastoma Treatment

Standard treatment of GBM is taking oral temozolomide every day during 6 weeks of radiation therapy 5 days a week. This is called chemoradiation therapy.

The 6 weeks of chemoradiation therapy is typically followed by six 28-day cycles when temozolomide is taken on days 1 to 5 of each cycle.

During the study, you will receive the same standard therapy and infusions of the study drug before every radiation therapy session.

Why is the study needed?

There have been no major advancements in the standard of care for GBM since 2006. Radiation therapy works better when the targeted tumor has a higher oxygen content. Unfortunately, GBM tumors typically have low oxygen levels. This study is investigating if NanoO₂ slows the growth of GBM tumors and increases the length of survival.

What is the RESTORE trial?

The RESTORE Study is being conducted to test a potential new drug called NanoO₂ for the treatment of GBM. RESTORE is a research study intended to determine if NanoO₂ improves the effectiveness of chemoradiation therapy on newly diagnosed GBMs, and to evaluate the safety of NanoO₂.

The RESTORE Study supplements the standard chemoradiation therapy described above. Participants who meet the selection criteria for RESTORE will undergo the standard chemoradiation, and will also be randomized to receive an infusion of NanoO₂ or saline infusion immediately before each radiation therapy session.

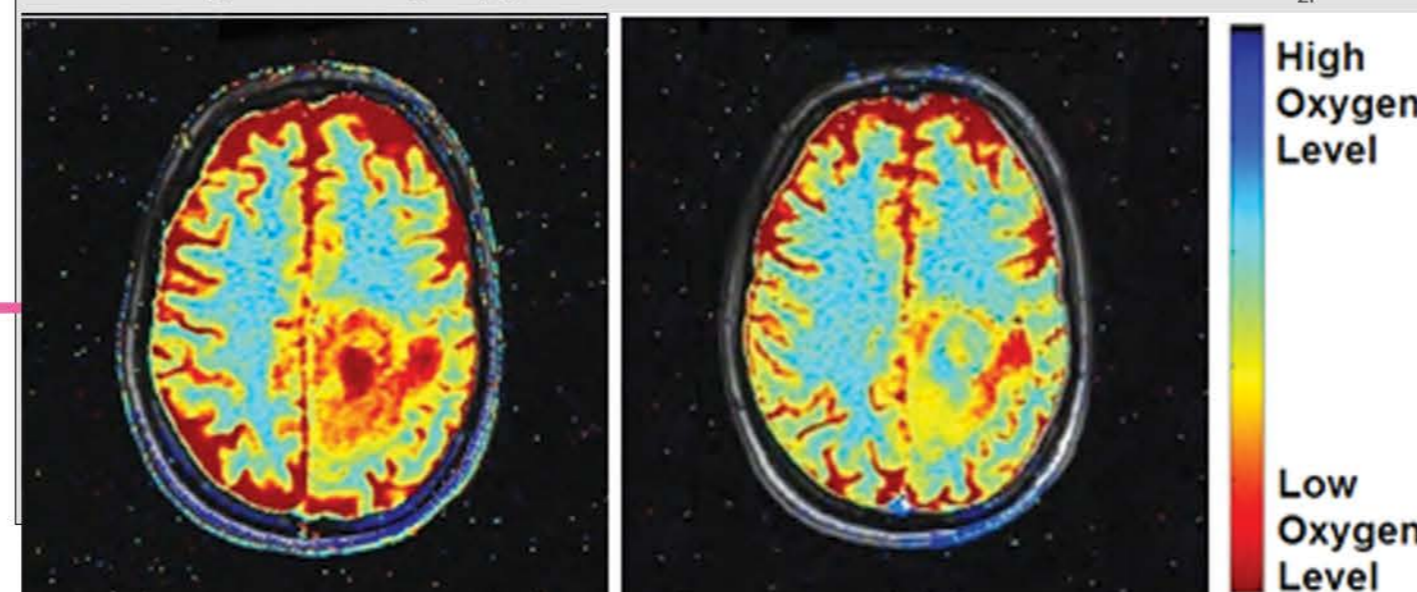
The RESTORE Study will compare the safety and effectiveness between patients who receive NanoO₂ and those who do not.

What is NanoO₂?

Tumors that have higher levels of oxygen respond better to radiation. NanoO₂ was developed to increase the amount of oxygen in the tumor cells.

NanoO₂ is an investigational drug which is intended to increase the oxygen in blood. It has not been approved by the FDA to treat GBM or any other disease.

MRI Images showing oxygen levels in the brain before and after NanoO₂.



How does NanoO₂ work?

NanoO₂ is infused into a vein and circulates with blood throughout the body. The infusion takes about 10 minutes.

Oxygen attaches to the NanoO₂ as it passes through the lungs to increase the amount of oxygen in the blood. The increased oxygen is available as blood travels throughout the body. NanoO₂ is exhaled through the lungs and 95% will be exhaled after about 7 hours.

Who is Eligible?

Male and females, 18 years or older with newly diagnosed Glioblastoma Multiforme.

The study team will review a detailed list of criteria that subjects must meet to be included in the trial.

Can I stop participating in the trial?

Participation in any research project is voluntary. Your decision whether to take part or not, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with your trial site and will not involve any penalty or loss of benefits.

The RESTORE Study is standard GBM Treatment with NanO₂ added

During the study, you will receive standard GBM treatment; AND you may receive infusions of NanO₂ before every radiation therapy session. You will stop receiving NanO₂ after your last radiation treatment.

Will I definitely receive NanO₂?

RESTORE participants will be randomized, like flipping a coin, to determine if they will get NanO₂ or receive the standard treatment with a saline solution. Study participants have about a 67% chance to receive NanO₂ therapy.

How long does the treatment last?

The treatment cycles are identical to standard GBM therapy.

Chemoradiation with study drug ~ 6 weeks

Recovery period without therapy ~ 4 weeks

Temozolomide Chemotherapy ~ 6 months

How long will I be in this Study?

Participation in the trial is approximately 5 years after the end of treatment.

- Follow up visits with your physician every 3 months for 3 years.
- Follow up phone calls every 6 months for 2 more years.

How often will I see my doctor?

You will see your doctor during the study at exactly the same visits as you would without participating in the study:

- Weekly during chemoradiation
- Monthly during Temozolomide chemotherapy
- Every 3 months after Temozolomide chemotherapy

What are the benefits of participating in the RESTORE Study?

- You will have access to a potential new treatment that is not available to people outside the study.
- The research team will watch you closely.
- You may be among the first to benefit from the new treatment if the study treatment is better than the standard treatment.
- The study results may help scientists learn more about GBM and help people in the future.

Are there possible risks to participating in the RESTORE Study?

- The potential new treatment may not be better than the standard treatment.
- The standard treatment has known side effects.
- There may be additional side effects with the study treatment.

**Mobilizing
Oxygen,
Transforming
Lives.**

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The RESTORE Trial is sponsored by
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