

FM474 Repetitive Transcranial Magnetic Stimulation (rTMS)

INFORMATION FOR CONSENT FORM

Introduction

Repetitive transcranial magnetic stimulation (rTMS) is a new treatment for depression and possibly other psychiatric disorders. Studies have clearly shown that rTMS is an effective treatment for patients with depression. This research is primarily focused on showing that rTMS can successfully treat an acute episode of depression. However, depression is a disorder characterised by recurrences, that is, symptoms can come back even when successfully treated. The research conducted to date that has utilised rTMS to treat recurrent episodes of depression, also clearly shows that there is a good chance of rTMS working in treating depression during subsequent episodes of depression if it has worked once before.

The following will provide further detailed information about rTMS and its use in the treatment of depression. You will need to read this information and sign the attached consent form before undergoing treatment.

What is rTMS?

rTMS is a procedure that involves the focused application of magnetic energy to superficial regions of the brain, thus inducing small electrical currents. During an rTMS procedure, an electrical current passes through a small coil placed close to the scalp. This current induces a magnetic field. The magnetic field can pass into the brain without resistance. If the magnetic field is of sufficient strength, it will stimulate electrical activity in nerves below the coil, that is, in superficial regions of the brain. This stimulation may be repeated many times per second and with variation in intensity: these variations will determine the effects of the stimulation – rTMS can be applied in differing ways to either increase or decrease local brain activity.

rTMS in Depression

Studies have evaluated the role of rTMS in the treatment of depression since the mid-1990s. These studies have clearly shown that rTMS is more effective than a sham or placebo type of stimulation, especially in patients who have not responded well to antidepressant medication treatment. It is not clear how rTMS works in depression. One theory is that the repeated stimulation alters the sensitivity of nerve cells in the front regions of the brain and alters how active these areas are.

What happens when you have rTMS?

rTMS is usually administered 5 days per week (Monday to Friday) but other schedules are possible. Sessions usually take between 20 and 40 minutes per day depending on the protocol being utilised. During an rTMS session a patient is awake, alert and aware of what is happening at all times. He/she sits in a comfortable chair.

Before the treatment course begins, some time will usually be spent stimulating the area of the brain that controls muscle movement in the hand opposite to the side of brain on which the rTMS will be given. The patient may feel small twitches in the hand during this procedure. It is not painful. This procedure is done to establish how high the machine intensity needs to

be sent to affect the brain in an individual patient.

During the treatment itself, a coil is usually placed on the scalp (held by hand or with a coil stand) near the front region of the brain. This may be on the left or right depending on how the treatment is being given. The coil is connected to a machine that generates the electrical current. The current produces no sensation as it does not come into contact with the body. As the magnetic field is produced by the electrical current being switched on and off, the machine produces a clicking sound although the patient will usually wear disposable ear plugs to prevent any discomfort from the sound. The patient may feel a tapping sensation under the coil (this occurs due to a twitch produced in the scalp muscles as the magnetic field crosses into the brain). The magnetic field can also stimulate small nerves around the head and face producing a muscle twitch in the forehead, face or eye region. The stimulation can be applied in a variety of ways: the most common two ways are either as a long train of pulses administered approximately one per second or as short bursts of a large number of pulses administered over a few seconds at a time.

If the rTMS is effective in treating depression, this usually takes several weeks. Most patients who respond feel different during the second or third week but they may not feel much better until they have had 3 or 4 weeks of treatment.

rTMS is usually given in a defined course to try and achieve a remission or substantial reduction in depression severity. Depression is a relapsing disorder and so it is likely that it will return after treatment for most patients some time in the future. Therefore, most patients are encouraged to continue with other treatments including antidepressant medications, especially to try and prevent relapse after the treatment with rTMS finishes.

Providing Repeated Courses of rTMS Treatment

Experience suggests that the majority of patients who have responded well to a course of rTMS will respond again when it is provided in the future. However, this does not necessarily apply to all patients, and so a patient's response to repeat treatment is not guaranteed.

In most patients, a repeat course of treatment will be provided in a manner identical to, or very similar to, the way in which rTMS was applied originally. Therefore, the patient's experience of the treatment and its possible side effects is likely to be very similar to the experience of rTMS treatment the first time the patient had it.

Side Effects

There are several potential side effects that might be experienced during an rTMS procedure. First, a headache or neck-ache can occur, similar to a tension headache, caused by the stimulation of nerves in the scalp. This occurs in approximately five of every one hundred participants studied and will often improve rapidly with simple pain medication such as 'aspirin' or 'panadol'. Second, the stimulation itself may be uncomfortable. As the magnetic field passes into the brain, it can cause stimulation of muscles in the scalp causing them to contract. This can feel like a twitch, a tapping sensation or a brief muscle cramp. How strong this feels varies dramatically between subjects: some feel almost nothing and others a stronger sensation. Those who do find it uncomfortable usually find they get used to the sensation over a few days and strength of the stimulation pulse can be lowered until then.

Risks

The main concern associated with rTMS is its potential to cause a fit or seizure. Safety guidelines to limit the dose of rTMS used started to be used in the late 1990's and there have been very few seizures with the treatment since then: the risk appears quite low. There is also no reason to suggest that if a patient has repeated courses of rTMS changes this risk at all.

Although the vast majority of research conducted to date suggests that rTMS is safe and without long-term side effects, few studies have looked at the effects of rTMS over a long period of time or study the effects of repeated courses of treatment. Therefore, it is possible that there are risks that we are not yet aware of.

You should always tell your doctor if you change your medication or experience other medical issues during a course of rTMS as medication changes or medical illness could affect the risk of seizure. We will ask you to wear ear plugs during rTMS treatment as there is a risk of hearing damage from the sound produced by the machine although this has not been shown in people undergoing rTMS. Although the vast majority of research conducted to date suggests that rTMS is safe and without long-term side effects, it is still possible that there are risks that we are not yet aware of.

There are several reasons why someone cannot have rTMS. These include a diagnosis of epilepsy, an active brain illness such as a recent stroke or anything that may be affected by the magnetic field. This can include metal implants in the head, surgical clips, cardiac pacemakers, implanted medication pumps or electrodes. rTMS may also be avoided if a patient has an unstable medical condition (for example heart disease) that could be exacerbated if they were to suffer a seizure. The safety of rTMS in pregnancy has not been evaluated and is not recommended at this time. If any of these conditions are relevant to you, it is very important that you let us know prior to undertaking treatment.

Other Treatments While undertaking rTMS

It is important to tell your doctor and our rTMS staff about any treatments or medications you may be taking, including non-prescription medications or herbal remedies and any changes to these during your participation with rTMS. We typically try and avoid significant changes to medication, or starting new medications that affect the brain, during a course of rTMS treatment as this is likely to confuse our understanding about what might have produced any therapeutic benefits with this treatment.



FM474

(Affix patient identification label here)

URN:

Family Name:

Given Names:

Date of Birth:

Sex: M F

Repetitive Transcranial Magnetic Stimulation (rTMS) CONSENT FORM

DECLARATION BY PATIENT

1. I, the undersigned..... hereby consent to undergo an acute course of rTMS treatment.
2. I acknowledge that I have been provided with a written information sheet explaining this treatment titled "*Repetitive Transcranial Magnetic Stimulation Information Sheet.*" I am aware that rTMS is a relatively new clinical treatment.
3. I acknowledge that the nature, purpose and contemplated effects of the rTMS treatment so far as it affects me have been fully explained to my satisfaction and my consent is given voluntarily.
4. I understand that repeated use of TMS has not been widely studied and may entail risks that are not known at this stage.
5. The detail of the TMS proposed has also been explained to me, including the anticipated length of time it will take, the frequency with which it will be performed, and an indication of any discomfort which may be expected.
6. I understand that I can change my mind at any stage, even after a course of treatment has begun, without affecting my future health treatment, or any other treatment of the condition for which rTMS has been proposed.
7. I have not been guaranteed the treatment will be successful, and I understand the treatment is not a long term cure for the condition, so I may still relapse in the future.
8. I am informed that no information regarding any medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity. However, an evaluation of the success of the treatment may be published in a format that will not identify me.

Patients Name: _____ Date: _____

Patient Signature: _____

DECLARATION BY DOCTOR

- I declare that I have explained the nature and consequences of rTMS and discussed the benefits and risks that particularly concern the patient.
- I have given the patient, and the patient's carer where involved, an opportunity to ask questions and I have answered these. I confirm that I have explained the nature and effect of this treatment to the above patient.

Psychiatrist Name: _____ Date: _____

Psychiatrist Signature: _____