Do You Suffer From Depression That Has Not Responded To Medications?

Date: 2012-08-10, 4:05PM EDT
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The Neurochemical Imaging Program in Mood Disorders at the Research Imaging Centre is conducting a brain imaging study to look at brain changes associated with Electroconvulsive Therapy (ECT) in people with Depression

Did you know:
- 50-80% of people achieve remission after a course of ECT
- ECT works by telling the brain to make new brain cells
- Treatment is given while you are asleep (general anesthesia) for 5-10 minutes
- Half of people who receive ECT for depression are not staying in hospital

Eligibility for the brain imaging study:
Age 18 to 80
Diagnosis of Major Depressive Disorder
Have not responded to several anti-depressant treatments
Women: not currently pregnant
Not currently taking any alcohol or street drugs
Otherwise healthy

Clinical assessment and compensation provided.

If you would like to know more about the study please call:
(416) 535 - 8501 Ext. 4729

ALL QUERIES ARE STRICTLY CONFIDENTIAL

For more information about programs and services at CAMH please visit www.camh.ca or call 416-535-8501 (or 1-800-463-6273)

- Compensation: compensation provided
- Principals only. Recruiters, please don't contact this job poster.
- Phone calls about this job are ok.
- Please do not contact job poster about other services, products or commercial interests.

PostingID: 3197114177

You may be eligible to participate if you are:

- ✓ Age 18 to 80 years old
- ✓ Diagnosed with depression
- ✓ Receiving ECT for the first time
- ✓ Not taking any street drugs

If you would like to know more about the study **please call: 416-535-8501 ext. 4729**

All Inquiries Are Strictly Confidential

The Neurochemical Imaging Program in Mood Disorders

Centre for Addiction and Mental Health

University of Toronto

camh
Centre for Addiction and Mental Health

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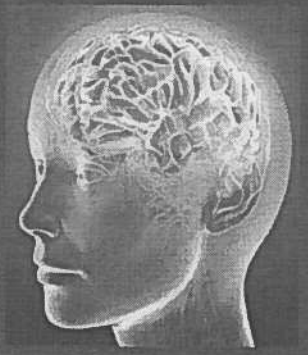
www.camh.net
or call (416) 535-8501
or 1-800-463-6273

Are you receiving ECT for depression?

Interested in participating in cutting edge research?

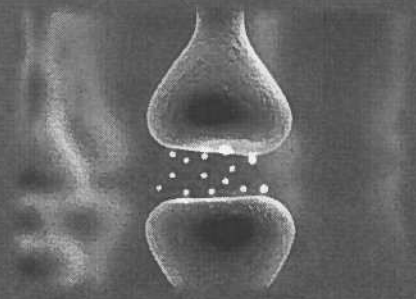


ECT works very well

- ✓ 50-80% of people achieve remission after a course of ECT; it's the best treatment to get people well
- ✓ ECT works by telling the brain to make new brain cells and increases mood supporting chemicals

Can we make ECT better?

After ECT there is a high risk of recurrence, though antidepressant medications can sometimes help prevent this



ECT and Inflammation?

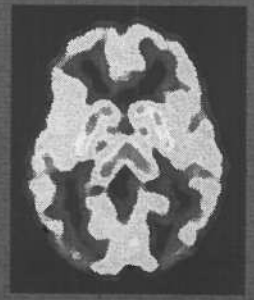
We think in the process of getting people well it is possible ECT may irritate the brain, an effect called inflammation.

This may explain why some people get a recurrence of illness.

How can brain imaging research help?

We have a new kind of brain scanning method that can detect whether the brain gets irritated.

If we detect this, future ECT could include a medication to prevent the irritation.



The Research Team

Two groups at CAMH are working together.

Neurochemical Imaging Program in Mood Disorders led by:

Dr. Jeffrey Meyer
MD, PhD, FRCP(C)
Canada Research Chair in Neurochemistry of Depression
Head, Neurochemical Imaging Program in Mood Disorders, Research Imaging Centre
Professor, Dept. of Psychiatry, University of Toronto

Centre for Therapeutic Brain Intervention led by:

Dr. Z. J. Daskalakis
MD, PhD, FRCP(C)
Director, Centre for Therapeutic Brain Intervention
Associate Professor, Dept. of Psychiatry, University of Toronto

camh
Centre for Addiction and Mental Health
Centre de toxicomanie et de santé mentale

Inflammation and Electroconvulsive Therapy

Study Information and Consent Form (Depressed Participant)

Investigators: Drs. Jeffrey H. Meyer, Z. Jeff Daskalakis, Sylvain Houle, Alan Wilson, Elaine Setiawan, Benoit Mulsant

Study Background and Purpose

Clinical depression affects a large number of individuals worldwide. Electroconvulsive therapy or ECT is the best treatment currently available for severe depression. We think that ECT works by stimulating the brain to make new brain cells and raising levels of mood supporting chemicals. However, after ECT there is a high risk of recurrence, though anti-depressant medications can sometimes help prevent this. We think that although ECT has proven benefits, there might be some side effects that lead to the problem of later recurrence of illness. One possible side effect is that ECT causes an irritation in the brain, called inflammation. No one has ever examined inflammation in the brain following ECT.

We are a team of psychiatrist practitioners and researchers working at the Centre for Addiction and Mental Health (CAMH), College Site and the CAMH Research Imaging Centre, an affiliated teaching hospital of the University of Toronto. We have a new technology developed here at CAMH that is excellent for looking at inflammation using brain imaging. In this study we will use Positron Emission Tomography (PET) imaging to measure translocator protein (TSPO), which is a marker of inflammation, before and after ECT in people with clinical depression.

We hope that our study will help improve ECT and the understanding of clinical depression. If we find increased inflammation, we may be able to use existing drugs to reduce this side effect of ECT.

In total, this study will have 30 participants.

If you agree to participate, you will have two Positron Emission Tomography (PET) imaging scans and two magnetic resonance imaging (MRI) scans. PET imaging measures brain chemicals and MRI imaging looks at certain chemicals and the shape and structure of the brain. You will also complete some questionnaires, memory tasks and provide urine and blood samples.

Preliminary Screening

You will have a visit with a research staff member to ensure that you meet the requirements to take part in the study. In this visit we will ask you about your medical and psychiatric history. To ensure that it is safe for you to participate in this trial, we will ask you for a urine sample, which is a standard requirement in the neuroimaging research studies. This visit will last approximately 2 hours.

Medications

To participate in this study, you may continue taking any anti-depressant medications that have been prescribed by your physician for the duration of the study.

You may continue to take lorazepam (Ativan) and clonazepam (Rivotril) as prescribed your physician and/or the ECT psychiatrist for the duration of the study.

You are asked not to use other benzodiazepines, eg. diazepam (Valium) within the month prior to the first PET scan and for the duration of the study. This is because these medications may interfere with our PET measure. If you need to take these medications you should not continue to participate in this study.

You are asked not to take any anti-inflammatory medications (examples: acetylsalicylic acid (Asprin), ibuprofen (Advil) and inhaled or oral corticosteroids (Flovent, Pulmicort, Deltasone)) for at least a month before the first PET scan and for the duration of the study. If you need to take these medications on a regular basis you should not continue to participate in this study.

The PET Brain Imaging Day

PET uses emissions from radiotracers injected in the bloodstream that go to the brain in order to measure brain function. Prior to PET scanning, one catheter will be placed in one of your radial arteries to allow us to obtain blood samples during the scan. Blood samples will be obtained during the scan to measure the amount of tracer in your blood. The measurement of the amount of tracer in your blood is used in combination with the brain scan to measure the TSPO in your brain. One blood sample will be used to obtain information about the level of certain proteins that may play a role in the inflammatory process.

A second catheter will be placed in one of your veins and will be used to inject the radiotracer. Altogether, a total of 170 ml of blood will be collected (about 40% of a blood donation).

To start, you will receive a small amount of radiation from a brief transmission scan to measure how much radiation is absorbed by your brain and the bones of your skull. For the PET imaging scan we will inject a small quantity of a radioactive substance, called [^{18}F]FEPPA, through a tiny needle into your forearm. [^{18}F]FEPPA binds to TSPO. This scan takes two hours. Each PET scanning session will require about 4-6 hours of your time. About 90 minutes of this time is spent completing questionnaires and memory tasks. Please note that [^{18}F]FEPPA is an investigational compound used for research purposes and not yet marketed in Canada.

Risks Involved With the PET Scanning Procedure

The radiation dose from this study is less than 6 mSv for both [^{18}F]FEPPA PET scans, well within the guidelines for this type of study (20mSv). The amount of radiation that you receive from natural sources during one year is about (3 mSv). The potential long-term risk from the radiation dose you will receive is uncertain but these doses have never been associated with any definite adverse effects. Thus the risk to you, if any, is estimated to be slight.

There will be a slight discomfort from the insertion of the intravenous line as well as the possibility of bruising. It is quite possible that you will have some temporary bruising from the arterial line. You will likely experience some discomfort from the insertion of the arterial line. More serious complications are rare but include aneurysm formation (local ballooning of the artery) or local thrombosis (blockage) of the artery, which may require surgical intervention to correct. Most subjects feel that arterial line placement is no more uncomfortable than voluntary blood donation. A physician who routinely puts in arterial lines will put in your arterial line.

Women Please Note: It is advised that pregnant women avoid all radiation to minimize any risk to the unborn child. You should not participate in this study if you are, could be, or plan to become pregnant during the study. A standard pregnancy test will be performed at each visit to our centre. If you change your mind about becoming pregnant during the study, please notify us immediately.

Risks Involved With the MRI Scanning Procedure

To help us localize various structures in your brain, we will also ask you to undergo a magnetic resonance (MRI) scan at CAMH and another at The Toronto General Hospital. New methods in magnetic resonance imaging are available at CAMH which give improved measurement of the structure of the brain and allow us to measure brain chemicals that are affected in clinical depression, such as n-acetyl aspartate. We still need the older MRI done at the Toronto General Hospital so that our PET imaging method is compatible with our earlier studies but the new MRI method will allow us to look at the relationship between the chemicals found with the MRI and the results found with the PET scanning. There is no known risk associated with this procedure unless you have metal implants. If you have metal implants (including metal fragments in your eye, pacemaker, surgical staples), you should not have an MRI. Metal braces for teeth and tooth fillings are compatible with receiving an MRI. Also, it is the policy of the hospital that you should not be pregnant at the time of the MRI scan. Before the MRI you will be asked to fill out a questionnaire with the research staff to ensure that it is safe for you to have an MRI. The major discomfort with MRI scanning is a knocking sound that the machine makes; earplugs will be available for you to decrease the noise. Some people may find the close space of the MRI scanner uncomfortable. It is not advisable for you to involve yourself in this study if you have a fear of closed spaces. About one hour will be required for each MRI scan. ***As the MRI scanner uses a magnetic field to generate the images, it is absolutely necessary that you do not have any mental implants in your body or a cardiac pacemaker.***

Risks Involved with ECT

The most troublesome side effect of ECT is memory loss. Recovery from that memory loss begins a few weeks after treatment and is usually complete within six to nine months. There may be a permanent loss of memory for details of some events, particularly those which occurred some time before and during the weeks the treatment is given. Also, there may be some difficulty learning and remembering new information for a short period after ECT. However, the ability to acquire new memories recovers completely usually a few months after treatment. Thus, the treatment does not cause a permanent loss of the ability to learn and remember events following the treatment. A very small number of patients report severe problems with memory that remain for months or years. Some patients experience a brief period of confusion after waking from the

anaesthetic. Some also experience muscle aches and headaches, but these are usually not severe and recover after a few hours.

ECT is given under general anaesthesia. Therefore, as with any treatment given this way, there is a risk of death but this is now rare, between two and four deaths being reported for every 100,000 treatments. The risk may be higher for patients who have other physical illnesses. The effect on any patient's physical illnesses on the treatment risk will be discussed with the patient. Also, very rare are bone fractures and broken teeth or other dental injury. Spontaneous seizures may occur some time after the treatment, but are rare.

Because of the time to recover fully from the general anaesthetic, patients must not operate a motor vehicle or any potentially dangerous equipment/machinery/tools until the day after each treatment.

These risks are identical to those found in the ECT Information for Clients/Patients form given to you during the consent process to receive ECT.

Confidentiality

All information about you collected during this study will be kept confidential and your identity will not be revealed when the results of this study are reported in presentations and publications. **To protect your confidentiality we will label ("code") your sample and your medical information with your initials and a number, not your name.** This number will be how researchers keep track of samples and information. Your name will not be in any publications or reports about this research. The samples will be kept for a period of not longer than 20 years after approval of the study.

By agreeing to take part in this research, you will allow your medical information and results to be audited by people who check that the research was done in accordance with the laws and regulations governing scientific research. As part of the Research Services Quality Assurance role, studies may be audited by the Manager of Quality Assurance. Your research records and CAMH records may be reviewed during which confidentiality will be maintained as per CAMH policies and to the extent permitted by law.

Reimbursement

You will be paid a total of $645 in recognition of your time involved for the entire study. Each PET scan with the arterial line is reimbursed at $210, each MRI scan at $50, genetic sample at $20. Hourly rate for questionnaires, memory tests and pencil paper tests done on the screening day and on the brain imaging day are reimbursed at $15/hour and this total time is estimated at 7 hours. Hourly rate for the scan day is $15/hour. The total time commitment required for the study is a maximum of 16 hours.

There will be no direct benefit to you from this study. You will help increase the knowledge of how the inflammatory process and its mechanisms may influence our understanding of major depressive disorder, electroconvulsive therapy, other related diseases and treatments. In the

future this knowledge may help diagnose such diseases and help to find new treatments that can be used earlier. In some cases, disease might be prevented.

If you agree, we may contact you in the future to invite you to participate in other studies. If you would not prefer to be contacted this will not affect your participation in this study.

Voluntary Participation

Your participation in this study is voluntary. You may choose to withdraw from the study at any time. In addition, the investigators or their staff responsible for this study may, at their discretion, end your participation at any time. If your participation ends early for whatever reason, you will be compensated on a pro-rated basis as described above. Your choice to not participate, your choice to withdraw, or your dismissal by us will not affect any treatment needs that you might have at the Centre for Addiction and Mental Health now or in the future.

Conclusion

If you agree to take part in the study, please sign this Informed Consent Form. Thank you in advance for considering this study. The study staff will be more than happy to answer any questions about research. Their contact details are given below:

Contact Dr. Jeffrey Meyer the principle investigator at telephone number (416) 535-8501 ext 4007 at any time if you have questions about this study or wish to withdraw from this research. If you have any questions about your rights as a research participant, contact Dr. Padraig Darby, Co-Chair, Research Ethics Board, Centre for Addiction and Mental Health, at (416) 535-8501 ext. 6876.

A copy of this Consent Form (signed and dated) will be given to you.

CONSENT

I _____
have read the above information and have been given the opportunity to ask further questions about this study. The study risks have been explained to me and my questions answered by

_____ .

I consent to participate in this research project to investigate TSPO in ECT. I understand that I will not benefit directly from this study. I understand that I may withdraw from this study at any time. I also understand that these PET scans are for research purposes only and that they are not part of any medical treatment. If I am a woman of childbearing age, it has been explained to me that I should not volunteer for this study if there is any possibility that I might be pregnant at the time of the study. If at any time during this study, there is a possibility that I could have become pregnant, I will inform the investigator and will not undergo further PET scanning.

At Toronto, on _____

_____
Your signature

_____
Witness

Should there be additional information that I could provide to help with this study, I am agreeable to being re-contacted in the future.

_____
Your signature