What is The SAMe Study?

Alzheimer's disease (AD) affects millions of people throughout the world and these numbers continue to increase, with no known cure or effective treatment to reverse the disease. The SAMe Study is a research project investigating a potential treatment for AD, called S-Adenosyl Methionine, or more commonly known as "SAMe". It is thought that AD may be caused by the toxic build-up of proteins in the brain such as tau and amyloid-beta. This study is looking at whether taking SAMe once a day will reduce tau protein levels.

You or the person you care for are invited to take part because you or they have been diagnosed with mild cognitive impairment or dementia due to Alzheimer's disease.

Research trials such as this are an important aspect of discovering new treatments for medical conditions. Participation is voluntary, and you will receive the best possible care whether you take part or not.

How does SAMe work?

There is research evidence to suggest that SAMe may reduce the levels of toxic tau in the brain. We will measure levels of tau in the blood at the beginning and end of the study to see if taking SAMe once a day helps to reduce tau levels.

What is involved?

Participants in the study will be asked to take 1 tablet a day for 6 months of SAMe or placebo. There will be 5 study visits plus 1 telephone call over a 7-month period. Some of these visits may be conducted in the participant's home. Participants will be assessed by a doctor who will perform a physical examination and take their medical history. Blood tests will be performed at 4 visits, and 2 visits will have memory and thinking tests.

To be eligible for the study, you or the person you care for must:

- Be aged 60 years or above
- Be diagnosed with mild cognitive impairment (MCI) or dementia due to Alzheimer's disease
- Have a close family member, friend or caregiver who can provide support and attend visits
- Be able to complete cognitive testing in English
- Have no diagnosis of bipolar affective disorder
- Have not had a stroke or transient ischaemic attack in the past 1 year
- Not be using anti-depressant medication at present

The study is being conducted by the Walter and Eliza Hall Institute of Medical Research in Parkville, Melbourne, and is sponsored by The University of Melbourne. The study is funded by an Alzheimer's Association research grant.

Principal Investigator: A/Professor Rosie Watson

Coordinating Principal Investigator: A/Professor Nawaf Yassi

Frequently Asked Questions

Will I receive the results from my tests?

You will receive results of the blood tests performed for safety reasons to monitor your general health. Any incidental findings of medical importance will also be discussed with your doctor. Genetic and tau blood testing results are for research purposes only and will not be disclosed to you.

What are the side effects of SAMe?

Side effects of SAMe are uncommon (fewer than 1 in every 100 people), and if they do occur, they are usually mild and temporary. Side effects may include headache, dizziness, feeling anxious or nervous, vomiting, nausea or upset stomach, flatulence and decreased appetite, diarrhoea, constipation, increased sweating, dry mouth or sleep problems. You will be monitored for such side effects.

Will I receive the study drug or the placebo?

The trial is double-blind which means that neither you, nor the research team will know whether you are receiving the study drug or the placebo. You have a 50:50 chance of being in either group. Designing trials in this way is crucial to ensure there is no bias in knowing what treatments participants are on.

What will happen to the information collected about me?

To protect your confidentiality, any information collected about you will be de-identified and replaced with a study ID number. Your identity will remain confidential to the study team and will not be shared outside of the research team.

Will I be out of pocket for any expenses?

No, all the study related procedures and the study drug are paid for by the study. We can provide complimentary parking at the site for visit attendance.

For more information about taking part please contact:

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This study is registered on the Australian New Zealand Clinical Trial Registry http://www.anzctr.org.au
Trial ID: ACTRN12620000506998This study is approved by the Melbourne Health Human Research Ethics Committee (HREC/52920/MH-2019)