

**Participant Information Sheet**

**Title:** The utility of Magnesium in the Management of Atrial fibrillation with Rapid ventricular response: A randomised controlled trial (MagMAR study)

**Principal Investigators:** A/Prof Andrew Teh

**Investigator Contact Details:** 0419 306 761

**Site:** Box Hill Hospital, 8 Arnold St, Box Hill 3128.

You are invited to participate in MagMAR, a clinical trial aimed at improving how we manage patients with an irregular and often fast heart beat called atrial fibrillation (AF).

Magnesium is thought to be useful in lowering heart rates in patients AF by altering electrical activity within the heart. It is therefore used by some doctors in patients who present to the emergency department with AF. However, it is debated how useful magnesium is, and current research in the area has produced conflicting results. Therefore, we wish to study it further to help decide if Magnesium should continue to be used to treat patients with AF.

The primary aim of this study is to identify if Magnesium is effective at slowing the heart rate of patients presenting to the emergency department (ED) with AF.

If you choose to participate in this study, you will be randomly placed in one of two groups and given either Magnesium in Sodium Chloride (salty water) or just Sodium Chloride via a drip for 30 minutes. You won’t know which group you are in and neither will your treating doctor or nurse. Some blood tests will be taken and you will be monitored in the ED.

Magnesium is a safe drug that is commonly used, its potential side effects are well known and we will be monitoring for them. Side effects from Magnesium are rare and short lasting, and in the vast majority of patients, no side effects are seen.

Potential side effects include:

* Sweating, flushing, feeling of warmth
* Nausea and vomiting
* Headache
* Muscle weakness
* Changes in your vision
* Temporary reduction in blood pressure

Potential benefits of participating include reduction in your heart rate and possibly improvement in associated symptoms however this cannot be guaranteed.

Your enrolment in this study is voluntary, if you don’t wish to take part you don’t have to. You will receive the best possible care whether or not you take part. If you do choose to participate but later change your mind, you can withdraw from the study at any time.

As part of the study we will need some of your personal details (name, gender, age and address) and medical history including your current medications. Any information obtained that can identify you will be treated as strictly confidential and stored securely.

Once we have collected data on a sufficient number of patients, it will be analysed to assess if Magnesium is effective in slowing fast heart rates in patients with AF. Results of this study may be published in a medical journal which will not include any personal or identifiable information.

This project is being undertaken by the Departments of Cardiology and Emergency, Eastern Health. Funding for this research has been provided by Eastern Health Foundation. Ethical aspects of this research have been approved by Eastern Health Human Research Ethics Committee in accordance with National Statement on Ethical Conduct in Human Research (2007).

Further information about the research can be obtained from contacting the principal researcher, Dr Andrew Teh (contact details above). Any concerns about the conduct of this research can be directed to the chairperson of the Eastern Health Human Ethics Research Committee. Tel: (03) 9895 3398 or Email: ethics@easternhealth.org.au

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

**Declaration by Participant – for participants who have read the information:**

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| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Declaration - for participants unable to read the information and consent form:**

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| Witness\* to the informed consent processName (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older. |

**Declaration by Doctor**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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| Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |