EMERALD STUDY

PARTICIPANTS WILL BE ASSIGNED BY CHANCE (CALLED RANDOMISATION) TO RECEIVE EITHER MEDICINAL CANNABIS OR PLACEBO. TREATMENT WILL CONTINUE FOR 180 DAYS, AND EACH PERSON WILL BE SEEN EVERY 3 MONTHS IN THE RESEARCH CLINIC (WITH MONTHLY TELEPHONE CALL IN BETWEEN).

YOU CAN HELP US BETTER UNDERSTAND HOW TO CURE OR TREAT MND. PARTICIPATION IS VOLUNTARY AND YOUR MEDICAL CARE WILL NOT BE COMPROMISED SHOULD YOU DECIDE NOT TO PARTICIPATE. IF YOU ARE INTERESTED IN BEING PART OF THIS IMPORTANT CLINICAL RESEARCH STUDY OR WOULD LIKE MORE INFORMATION, PLEASE CONTACT A MEMBER OF THE STUDY LISTED IN THIS LEAFLET.

THANK YOU.



Assoc Prof Arman Sabet Mr Berzenn Urbi Gold Coast University Hospital 1 Hospital Blvd., Southport 07 5687 4551 1300 744 728

Berzenn.Urbi@health.qld.gov.au



WHAT IS THE STUDY TESTING?

This is a study looking at the effects of medicinal cannabis in a liquid form in treating patients suffering with Amyotrophic Lateral Sclerosis (ALS) or Motor Neurone Disease (MND). ALS is a neurodegenerative disease that has an unknown cause and still remains with no cure. Patients with ALS usually live within 2-5 years post diagnosis.

The study team will treat 30 ALS patients over a 6-month period with either medicinal cannabis or placebo to evaluate protective mechanisms of cannabis that could help delay disease progression. If you agree to participate in this study, you will be asked to:

 Take study medication every day for 180 days.

2. Come to the clinic every 3 months and answer monthly telephone calls from study team until the end of study.

You will not know which medication to which you have been assigned until the end of the study. We will not interfere with any other medication you are taking, and you will remain under the care of your physicians.

if you wish to learn more about this project, please contact us. We will be happy to answer your questions and contact your primary doctor. We hope to learn the more about preventive treatment for patients with ALS/MND.

WHO IS ELIGIBLE TO PARTICIPATE?

- Patients with ALS/MND diagnosis, (either definite or probable)
- Male or female, ages 25 to 75
- First symptom started within the last 2 years
- Has no significant respiratory problems.

There are several other criteria that we will review if you are interested to participate.

Please note: It is a study and legal requirement that all patients taking medicinal cannabis will not be allowed to drive any vehicle and operate dangerous machineries.

WHAT IS AMYOTROPHIC LATERAL SCLEROSIS OR MOTOR NEURONE DISEASE?

ALS/MND is characterised by progressive degeneration of the motor nerve cells in the brain and spinal cord. The motor cells (neurones) control the muscles that enable us to move around, speak, breathe, and swallow. With no nerves to activate them, muscles gradually weaken and waste. Symptoms may include muscle weakness and paralysis, as well as impaired speaking, swallowing, and breathing. Progress is generally rapid, with an average life expectancy of between 2 and 5 years from the onset of symptoms