Pharmacogenetics for Severe Mood Disorders: A Randomised Controlled Trial

Hopwood., M., Komiti, A., Hurley, M., Villen-Peinado. M. Research Unit, Ramsay Clinic Albert Road

Introduction

Major Depression (MDD) and Bipolar Disorder (BD) are common and highly disabling conditions. Rates of response to current treatments are suboptimal, in part due to common variations in genes involved in how medications are processed in the body. This can affect how a person responds to medications.

The Amplis -EVO™ genetic test was developed to look at the variations in 16 genes known to be associated with how the body breaks down, transports and processes psychotropic medication through the liver as well as through the blood-brain barrier. Through a simple cheek swab, the results of the test may be used as a guide by doctors to select appropriate psychotropic medications and dosage levels based on individuals' genetic profile.

This study aims to further evaluate how effective the Amplis - EVO™ genetic test is, in assisting prescribing decisions for mood disorders, and to provide information for informed policy changes associated with treatment of mood disorders.

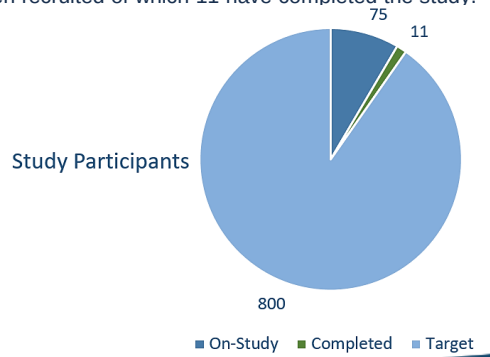
Methods

A 24-week, 2-arm, single-blinded, randomised control trial (RCT) to assess the clinical utility of Amplis-guided versus Standard (unguided) prescribing in the treatment of MDD and BD.

This recruitment target is 800 (400 per arm). Patients admitted to Ramsay Clinic Albert Road will have their admission documentation pre-screened for the inclusion/exclusion criteria. Participants are randomly assigned to the Amplis-guided or standard (unguided) prescribing arm using a 20 x 50 permuted block randomisation scheme. The participants' treating clinicians are informed of their recruitment into the study, randomisation allocation, and provided with the study visit schedule. Clinicians are encouraged to use the Amplis report to support prescribing decisions however, it is not mandatory. Study visits will occur at Weeks: 4, 8, 12 and 24 post-baseline. The following assessments are conducted by the Blinded Assessor at each time-point: PHQ-9, MADRS, YMRS (for BD only), MMAS-8, FIBSER scale.

Results

Recruitment commenced in February 2022 and is ongoing. To date, 86 individuals have been recruited of which 11 have completed the study.



Conclusions

The study is still in recruitment phase and to date, has been well received and has generated interested amongst patients and staff .

Acknowledgments

- The University of Melbourne
- The Ramsay Clinic Albert Road Research Unit

Funding

Ramsay Hospital Research Foundation

Contact Information

Angela Komiti
Research Unit
Ramsay Clinic Albert Road
03 9279 3569
research.arc@ramsayhealth.com.au

Ramsay Health Care