ETHICS APPROVAL

This study has been approved by the Sydney Local Health District CRGH HREC (2019/ETH00489) and is registered on the Australian New Zealand Clinical Trials Registry (ACTRN12619000562178p).

FUNDING

The research is funded by Daiwa Pharmaceutical Co., Ltd. (Daiwa) and BioMedica Nutraceuticals Pty. Ltd. Daiwa also manufactures and supplies the RBAC and placebo powder.

Note: *This is a summary of an ongoing clinical trial. Decision to participate in a clinical trial should not be based on this summary. Please refer to the official RBAC-QoL Participant Information Sheet (version 1.4 25/2/2020) for more detail.*

IF YOU ARE INTERESTED IN PARTICIPATING, PLEASE CONTACT:

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Charles Sturt University

RBAC-QoL Study

Charles Sturt University

Researchers at Charles Sturt University are doing a study to see if a rice bran supplement improves the quality of life of cancer patients during treatment.

Document version: 2.3 (28/08/2020)

WHY ARE WE DOING THIS STUDY?

Rice bran arabinoxylan compound (RBAC) is a food supplement known to affect the body's ability to defend against germs and cancerous cells.

During cancer treatment, RBAC may also help to reduce side-effects, make patients feel better, and may improve treatment results. However, there is not enough research to prove this.

This study hopes to see whether these benefits are true.

HOW DO I GET INVOLVED?

The research study is looking to recruit people who meet the following criteria:

- Age 18 years old and above
- Diagnosed with cancer (stage II and above)
- Currently receiving cancer treatment
- Blood tests for bone marrow, liver, and kidneys are within acceptable ranges

If you fulfil the above criteria and are interested, please contact us for more details for participation.

WHAT WILL I BE ASKED TO DO?

You will be asked to consume 3g/day RBAC or dummy (placebo) powder for 6 months.

The following will be collected at the start of participation and 4 times during the study period, 6 weeks apart:

- Complete a set of online questionnaires
- Visit a local pathology lab for
  1. Blood tests
  2. Body scan with weight, muscle, and fat measurements
  3. Stool sample collection (optional)

PATICIPATION TIMELINE

Provide study information, obtain informed consent

Screening by inclusion/exclusion criteria

Assign to consume RBAC or placebo by chance

Baseline assessment (Week 0)

Follow-up assessment (Week 6,12,18)

Final assessment (Week 24)