

Investigator Initiated Research (Version 2 – September 15, 2020)

Title:

Is 100% pure Stabilized Whole Rice Bran (SWRB) effective when used as a cleanser and an emollient in patients with mild to moderate atopic dermatitis?

- Information leaflet
- Instructions to participants/patients/parents
- Consent form
- Assent form
- Questionnaire for patient/parent

Information Leaflet for the Parent/Guardian and Participant
(Version 2 - September 15, 2020)

1. You / Your child will be participating in a clinical trial the results of which may be published in a medical journal.
2. The purpose of the trial is to determine whether 100% pure stabilized whole rice bran (SWRB) is effective when used as a cleanser and an emollient in patients with mild to moderate atopic dermatitis
3. The same 100% SWRB will be given to all participants with the same instructions
4. Instructions on how to use the product is attached herewith
5. Please follow the instructions given and report resultant effects, either orally or with pictures The trial involves only application of the product on the skin as a cleanser or emollient. This product is free of any additives, chemical and preservatives and hence should be kept dry and should not come in contact with water in the container.
6. In Asia, over the generations, rice powder has been applied to the face for beautification effects. However, this has not been documented well. This project is an experimental trial to document the most nutritious part of the rice grain i.e. Rice Bran.
7. This product is 100% rice based and is edible. Limited studies available have shown Rice Bran is safe on the skin. However, since it has rice protein, there is a minimal risk that it can cause skin irritation albeit mild.
8. SWRB is said to moisturize and rejuvenate the skin. Hence, it is expected that the skin should have a better texture and be less irritated after the 6 weeks of using this product.
9. There are several skin care products available in the market for Atopic Dermatitis that should have similar effects but none that is edible.
10. In the unlikely event that there is a reaction to this product, Dato' Dr. S. Sellappan will advise and issue remedial therapy as required. Such remedial therapy may incur additional expenses because of additional visits to see the doctor or medicines required to treat it.'
11. It is anticipated that expenses reimbursable to the participants would be maximum RM100
12. If any expense is required by the participant, Rice Bran Nutraceuticals will compensate the amount to a maximum of RM100 per participant.

13. It is understood that your child are is participating in this trial is voluntarily and that you may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which you be otherwise entitled.

14. The monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to your child's original medical records for verification of clinical trial procedures and/or data, without violating your confidentiality, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, you are authorizing such access.

15. Your child's record and identity will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, your child's identity will remain confidential.

16. You will be informed in a timely manner if information becomes available that may be relevant to your child's willingness to continue participation in this trial.

17. You can contact the medical personnel dispensing the SWRB to you or the principal investigator (Dato' Dr S. Sellappan) regarding the trial, your rights and in the event of the trial-related injury.

If you have questions about the rights of research participants, please contact the Chairman of the Joint Penang Independent Ethics Committee (JPEC) c/o Dr. Tan May Loong, RUMC , 4 Jalan Sepoy Lines, 10450 George Town, Penang.

18. The trial is for six weeks and the SWRB is considered safe. It is not likely that you/your child will not be able to finish the trial. One circumstances under which the you/your child's participation in the trial may be terminated is if you/your child develop an adverse reaction to the SWRB

19. You/your child would be expected to participate in this study for a period of 6 weeks.

20. You/your child will be one of upto 100 participants in this study.

21. SWRB does not contain any ingredient originating from cows or pigs which may be culturally unacceptable among Hindus and Muslims

Instructions to patients for use of SWRB as cleanser
(Version 2 – September 15, 2020)

For external use only

Direction for Use

- Wet skin with lukewarm water.
- Add a small amount of water and sprinkle the product onto your palm.
- Rub hands together and apply to skin using circular motions.
- Rinse with water
- Use once or two times a day

Keep Dry & Store in a Dry Place

Instructions to patients for use of SWRB as a moisturizer
(Version 2 – September 15, 2020)

For external use only

Direction for Use

- Sprinkle the required amount of product onto a clean plate
- Add enough lukewarm water to make a paste
- Apply this paste to the affected area and leave to dry overnight
- Rinse off the next morning

Keep Dry & Store in a Dry Place

**Informed Consent Form by Parent / Guardian for participation in the study
“Is 100% pure Stabilized Whole Rice Bran (SWRB) effective when used as a
cleanser and an emollient in patients with mild to moderate atopic dermatitis?”
(Version 2 – September 15, 2020)**

I have read the information and instruction leaflets / it has been read to me on using Stabilised Whole Rice Bran as a cleanser / emollient. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant _____

NRIC No. of Participant _____

Address of Participant _____

Signature of Parent / Guardian _____

NRIC No. of Parent / Guardian _____

Address of Parent / Guardian _____

Date: day of 2020

I have witnessed the accurate reading of the consent form to the parent/parents/participant, and they have had the opportunity to ask questions. I confirm that they have given their consent freely.

Print Name of Witness _____

NRIC No. of Witness _____

Signature of Witness _____

Date: day of 2020

Statement by the researcher/person taking consent

I have accurately read out the information & instruction leaflets to the potential participant's Parent / Guardian, and to the best of my ability made sure that the Parent / Guardian understands objectives, benefits, risks and other relevant features of the study as per the information leaflet.

I confirm that the parent/guardian and participant was given an opportunity to ask questions about the study, and all the questions asked by the them have been answered correctly and to the best of my ability. I confirm that they have not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Investigator _____

NRIC No. of Investigator _____

Address of Investigator _____

Signature of Investigator _____

Date: day of 2020

Assent form

(Version 2 - September 15, 2020)

Study title: Is 100% pure stabilized whole rice bran (SWRB) effective when used as a cleanser and an emollient in patients with mild to moderate atopic dermatitis?

Investigators:

Principal investigator (PI): Dato' Dr S Sellappan

Co-investigator: Dr Harinarayan Radhakrishna

We are doing a research study. A research study is a special way to find out something. We want to find out if stabilized rice bran (SWRB) is effective when used as a cleanser and a moisturiser on people with a skin condition such as yours.

You can be in this study if you want to. If you want to be in this study, you will be asked to apply this medicine on your affected skin areas and see the doctor regularly.

If you choose to be in this study, some good things may happen to you. Your skin condition may improve. However, it may also stay the same. Some people may develop allergic reactions to the SWRB.

If you don't want to be in this study, we will tell you about the other things we will do to help you.

When this study is over, we will be writing a report about what we find out. We will not be mentioning your name in that report.

You do not have to be in this study. You can say 'no' and nothing bad will happen. If you say 'yes' now and want to say 'no' later, it is all right to do so. No one will hurt you or punish you.

If you want to be in this study, please sign your name.

I, _____ NRIC No. _____
(write your name here)

want to be in this study.

Signed before me: _____
(investigator signature)

Date: _____ day of _____ 2020

**Questionnaire for patient / parent/s or legal guardian
(Version 2 – September 15, 2020)**

Name: _____

Date: _____

1. How satisfied are you with the effectiveness of the Stabilised Whole Rice Bran Powder Cleanser in treating Eczema, Dry Skin or healing damaged skin?

- ☐ Very Satisfied
- ☐ Somewhat Satisfied
- ☐ Neither Satisfied Nor Dissatisfied,
- ☐ Somewhat Dissatisfied
- ☐ Very Dissatisfied

2. How often would you prefer to use the Powder Cleanser?

- ☐ Twice a day
- ☐ Once a day
- ☐ Once every other day
- ☐ Once in two days
- ☐ Once a week

3. How satisfied are you with the method the Powder Cleanser is applied to the skin?

- ☐ Very Satisfied
- ☐ Somewhat Satisfied
- ☐ Neither Satisfied Nor Dissatisfied
- ☐ Somewhat Dissatisfied
- ☐ Very Dissatisfied

4. How satisfied are you with the look and feel of the Powder Cleanser Dispenser?

- ☐ Very Satisfied
- ☐ Somewhat Satisfied
- ☐ Neither Satisfied Nor Dissatisfied,
- ☐ Somewhat Dissatisfied
- ☐ Very Dissatisfied

5. How do you feel about the smell of the powder cleanser

- ☐ Acceptable
- ☐ Not acceptable
- ☐ Natural smell

6. Do you have any inconveniences in using the powder cleanser or emollient?

☐ Yes

☐ No

If yes, please explain: _____

7. How would you rate the value for money of the Powder Cleanser if the 100 gram powder dispenser sells for RM20?

☐ Excellent

☐ Above Average

☐ Average

☐ Below Average

☐ Poor

8. How likely are you to use the Powder Cleanser in the future?

☐ Extremely likely

☐ Very Likely

☐ Somewhat Likely

☐ Not so Likely

☐ Not at all Likely

9. How likely is it that you would recommend this product to a friend or colleague?

Not at all Likely

Extremely

Likely

0

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If answer to No.8 above is Interested, please provide us your email address

10. Do you have any safety concerns regarding the powder cleanser / emollient

☐ Yes

☐ No

If yes, please elaborate: _____

THANK YOU VERY MUCH FOR TAKING TIME TO COMPLETE THIS SURVEY.