

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Efficacy of Lotion Containing Black Rice Bran (*Oryza sativa L. indica*) Extract with Placebo as Skin Brightening Agent with in Healthy Asian Women

#### Protocol summary

##### Study aim

This research is about black rice bran extract which is formulated into lotions which have great potential as a skin care product to brighten the skin.

##### Design

Parallel group trial with double blinded application of lotion

##### Settings and conduct

Each participants are applying lotion A in left elbow and lotion B right elbow twice a day (every morning and evening) for 14 days. Both participants and researchers are blinded

##### Participants/Inclusion and exclusion criteria

woman, Asian race, age range 18-25 years; healthy skin condition; has no history of allergies; not pregnant or breastfeeding; has no chronic medical history,, does not have tattoos, scars or burns; not currently using therapies such as anti-inflammatory, corticosteroids, hormonal contraceptives, or lasers; and do not smoke, do not drink alcohol and do not use drugs, do not orally consume the test substance (black rice bran extract) and skin brightening agent.

##### Intervention groups

Lotions containing extract and placebo were applied twice a day in both elbow

##### Main outcome variables

The skin melanin after application of lotions were measured with mexameter

#### General information

##### Reason for update

##### Acronym

BRBCT

##### IRCT registration information

IRCT registration number: **IRCT20210412050942N1**

Registration date: **2021-05-01, 1400/02/11**

Registration timing: **retrospective**

Last update: **2021-05-01, 1400/02/11**

Update count: **0**

##### Registration date

2021-05-01, 1400/02/11

##### Registrant information

###### Name

Affiah Vardhani

###### Name of organization / entity

Universitas Indonesia

###### Country

Indonesia

###### Phone

+62 622 74372722

###### Email address

afifah.kusuma@ui.ac.id

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-01, 1398/10/11

##### Expected recruitment end date

2020-03-23, 1399/01/04

##### Actual recruitment start date

2020-01-01, 1398/10/11

##### Actual recruitment end date

2020-02-23, 1398/12/04

##### Trial completion date

2020-03-12, 1398/12/22

##### Scientific title

Comparison of the Efficacy of Lotion Containing Black Rice Bran (*Oryza sativa L. indica*) Extract with Placebo as Skin Brightening Agent with in Healthy Asian Women

##### Public title

Efficacy of Lotion Containing Black Rice Bran (*Oryza sativa* L. indica) Extract as Skin Brightening Agent, a Clinical

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

healthy skin condition; Asian race

### Exclusion criteria:

history of allergies; pregnant or breastfeeding; chronic medical history, have tattoos, scars or burns; currently using therapies such as anti-inflammatory, corticosteroids, hormonal contraceptives, or lasers; smoke, drink alcohol and use drugs, orally consume the test substance (black rice bran extract), apply and consume skin brightening agent topically or orally

## Age

From **18 years** old to **25 years** old

## Gender

Female

## Phase

1

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

one sample is lotion containing extract, another is placebo lotion

Actual sample size reached: **34**

More than 1 sample in each individual

Actual sample size in each individual: **2**

one sample is lotion containing extract, another is placebo lotion

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants will be given 2 types of lotions to use on right and left elbows, which are applied evenly until they are absorbed. The lotions given have been coded, namely code A-right and code-B-left. This study lasted for 2 weeks (14 days). Every day, participants have to use the lotion for 14 days, twice a day in the morning and evening, each of approximately 1 gram by first washing participants' hands which will be smeared with the lotion and wiped dry. Participants are also asked to rub code A lotion on the back of participants' right hand using the finger of participants' left hand, and apply code B lotion to the back of participants' left hand using the finger of participants' right hand. This is done to prevent lotion A and lotion from mixing. Apply using participants' fingers until all of the lotion is evenly spread and absorbed well.

Participants' are prohibited from washing hands at least 1 hour after using the product. Day 14, the use of the lotion is stopped and the researchers will re-check some parameters of participants' skin's brightness level with a Mexameter tool.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Ethics Committee, Faculty of Medicine, University of Indonesia

##### Street address

Salemba Raya No 6

##### City

Jakarta

##### Postal code

10430

#### Approval date

2019-12-09, 1398/09/18

#### Ethics committee reference number

19-10-1170

## Health conditions studied

### 1

#### Description of health condition studied

Healthy skin condition

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Melanin index

#### Timepoint

2 weeks after intervention

#### Method of measurement

Measure skin melanin index with mexameter

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: one lotion containing black rice bran extract 10% is applied in one side of volunteer's volar. each application of lotion is 0,5 gram, applied in diameter 5 centimeters. Lotion is applied twice a day (every morning and evening after shower) for 14 days. the excipients of lotions are demineralized aqua, olive oil, vaseline album, dimethicone. Cetyl alcohol, isopropyl myristate, span 80, propylparaben, BHT, tween 80, methylparaben, and glycerin. They are manufactured by Brataco (Indonesia)

### Category

Treatment - Other

## 2

### Description

Control group: one placebo lotion were applied in the other side of volunteer's volar. each application of lotion is 0,5 gram, applied in diameter 5 centimeters. Lotion is applied twice a day (every morning and evening after shower) for 14 days. the excipients of lotions are demineralized aqua, olive oil, vaseline album, dimethicone. Cetyl alcohol, isopropyl myristate, span 80, propylparaben, BHT, tween 80, methylparaben, glycerin and colorant. They are manufactured by Brataco (Indonesia)

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Faculty of Pharmacy, University of Indonesia

#### Full name of responsible person

dr. Afifah Kusuma Vardhani

#### Street address

Semanggi Hill B5 Jl. Zakaria

#### City

Depok

#### Postal code

16426

#### Phone

+62 622 74372722

#### Email

afifah.felani@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Integrated Laboratory and Research Center,  
University of Indonesia.

#### Full name of responsible person

Dede Djuhana, Ph.D

### Street address

Lingkar Kampus UI

### City

Depok

### Postal code

16424

### Phone

+62 622 17270152

### Email

drpm@ui.ac.id

### Web page address

<https://research.ui.ac.id/research/>

### Grant name

QQ Grant

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Integrated Laboratory and Research Center, University of Indonesia.

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

University of Indonesia

#### Full name of responsible person

Afifah Kusuma Vardhani

#### Position

Post graduate

#### Latest degree

Master

#### Other areas of specialty/work

Dermatology

#### Street address

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## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

University of Indonesia

**Full name of responsible person**

Afifah Kusuma Vardhani

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

University of Indonesia

**Full name of responsible person**

Afifah Kusuma Vardhani

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available