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Zinc biofortified rice efficacy trial

Submission date	Recruitment status	[X] Prospectively registered
26/09/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/10/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/11/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Zinc deficiency is common among women and children in low- and middle-income countries (LMICs) due to their plant-based diets, which lack zinc and contain factors that prevent zinc absorption. To address this, we are testing zinc biofortified rice as a potential solution. Previous studies with biofortified crops like wheat, rice, and pearl millet did not show significant improvements in zinc levels. Therefore, we are conducting a community-based randomized controlled trial to test the effectiveness of zinc-biofortified rice in improving zinc status among young women in rural Bangladesh.

Who can participate?
Young non-pregnant, non-lactating (NPNL) women aged 20 to 29 years living in the rural area of Birganj, Dinajpur in Bangladesh can participate in this study.

What does the study involve?
Participants will be divided into two groups. One group will receive high-zinc biofortified rice (ZBR) for themselves and their families for three months. The other group will receive low-zinc conventional rice (CR) for the same period. We will conduct surveys at the beginning and end of the study to collect data on health and diet, and blood samples will be taken to measure zinc levels and other health markers. We will also test the rice for zinc content before and after cooking.

What are the possible benefits and risks of participating?
Participants will receive a supply of rice for their families for three months and will get their blood test results. The study poses minimal risk, with the main discomfort being blood sample collection. All precautions will be taken to ensure safety. The study's findings could help policymakers promote zinc-biofortified rice, benefiting the wider population.

Where is the study run from?
The study is being conducted by Griffith University in Queensland, Australia, in partnership with BRAC James P Grant School of Public Health, BRAC University in Bangladesh.

When is the study starting and how long is it expected to run for?
August 2023 to March 2025

Who is funding the study?
Nestle Foundation (Switzerland)

Who is the main contact?
Dr Faruk Ahmed, f.ahmed@griffith.edu.au

Contact information

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Scientific, Principal investigator

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Additional identifiers

Protocol serial number
Griffith University IRB Ref No: 2023/611

Study information

Scientific Title
Efficacy of zinc biofortified rice for preventing zinc deficiency in Bangladesh: a randomized controlled trial

Study objectives
The study hypothesizes that consuming zinc-biofortified rice for three months is going to improve zinc status, measured by plasma zinc concentration, among young non-pregnant non-lactating rural women (aged between 20-29 years) in rural Bangladesh compared to consumption of low-zinc conventional rice for the same duration.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 25/08/2023, Human Research Ethics Committee (EC00162) (Research Ethics and Integrity, Office for Research, Bray Centre (N54), Nathan Campus, Griffith University, Brisbane, 4111, Australia; +61 737352069; research-ethics@griffith.edu.au), ref: 2023/611

2. Approved 03/06/2024, Institutional Review Board, BRAC James P Grant School of Public Health, BRAC University (65, Bir Uttam AK Khandakar Road, Mohakhali, Dhaka, 1212, Bangladesh; +88-2-48812213-18; irb-jpgsph@bracu.ac.bd), ref: IRB-2024-IS-08

Primary study design
Interventional

Study design
Community-based interventional randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Plasma zinc concentration, among young non-pregnant non-lactating rural women

Interventions
This will be a community-based randomized controlled trial where the participants will be assigned into two arms, using simple random sampling. participants in the intervention arm will

receive a raw rice supply of zinc-biofortified rice (ZBR; BRRI-100 variety) for three months for themselves and their family members, and participants in the control arm will receive a raw rice supply of low-zinc conventional rice (CR) for themselves and their family members for the same duration.

The participants are asked to consume the supplied rice ad libitum along with their habitual diet (other food items except rice).

Baseline and endline surveys will be carried out to detect the difference in plasma zinc concentration among the study participants and determine the treatment effect.

Compliance will be monitored, and dietary intake will be assessed to estimate zinc intake during the study period.

Intervention Type
Other

Primary outcome(s)
Plasma zinc concentration, measured from plasma sample collected at baseline and 3 months (endline) analysed by atomic absorption spectrometry. The value will be further adjusted for serum C-reactive Protein (CRP) and alpha-1 acid glycoprotein (AGP) which will be measured from serum using commercial ELISA kits at similar timepoints.

Key secondary outcome(s)
Current secondary outcome measures as of 07/10/2024:
1. Zinc deficiency measured as the fraction of participants having a PZC level below the cutoff of the normal range provided by the International Zinc Nutrition Consultative Group (IZiNCG) for the age and sex of the individual. The outcome will be measured at baseline and 3 months (endline).
2. Morbidity measured by the frequency and duration of common morbidities such as fever, diarrhoea, sore throat, cold and cough, body pain, and vomiting. The data will be collected at baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks and 12 weeks (3 months, endline) from the participants (self-report), converted into longitudinal prevalence (LP) and compared between two arms.

Previous secondary outcome measures:
1. Zinc deficiency measured as the fraction of participants having a PZC level below the cutoff of the normal range provided by the International Zinc Nutrition Consultative Group (IZiNCG) for the age and sex of the individual. The outcome will be measured at baseline and 3 months (endline).
2. Morbidity measured by the frequency and duration of common morbidities such as fever, diarrhoea, sore throat, cold and cough, body pain, and vomiting. The data will be collected from the participants (self-report) at baseline and 3 months (endline).

Completion date
31/03/2025

Eligibility

Key inclusion criteria

1. Healthy non-pregnant, non-lactating women aged between 20 and 29 years.
2. Residing in the study area and intending to live there for the next six months.
3. Did not consume any micronutrient supplementation (including iron folic acid supplementation) in the preceding 3 months.
4. Not recipients of ration from any government safety net programs.
5. Willing to participate in the study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit
29 Years

Sex
Female

Total final enrolment
197

Key exclusion criteria
1. Participants having any acute, sub-acute or chronic condition that prevents them from complying with the study procedure.
2. Participants whose families are recipients of ration from any government social safety net program.

Date of first enrolment
14/11/2024

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Australia

Bangladesh

Study participating centre

BRAC James P Grant School of Public Health, BRAC University
65, Bir Uttam AK Khandakar Road, Mohakhali
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Study participating centre
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Sponsor information

Organisation
Nestlé Foundation

ROR
https://ror.org/021k07d19

Funder(s)

Funder type
Research council

Funder Name
Fondation Nestlé

Alternative Name(s)
Nestlé Foundation, Fundación Nestlé

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			29/11/2024	No	Yes