Zinc and Iron Bioavailability From Biofortified Pearl Millet

STUDY DESCRIPTION

Brief Summary

Populations who consume non-fortified plant-based diets are at increased risk of iron and zinc deficiencies. The purpose of this randomized controlled study is to determine the absorption of iron and zinc from pearl millet biofortified with these two micronutrients. Forty children aged 2 years in Kanartaka, India, are randomized to consume biofortified pearl millet (Group 1) or control pearl millet (Group 2) for two days. Quantities of zinc and iron absorbed are measured with established stable isotope extrinsic labeling techniques and analyses of duplicate diets.

Condition or Disease: Nutritional Deficiency

Intervention/treatment:
- Other: Pearl millet
- Other: Biofortified pearl millet

Phase: Not Applicable

DETAILED DESCRIPTION

Nutritional deficiency of iron in 30-70% of young children in different communities in India is well documented and has proved challenging to eradicate both in India and globally. Less is known about zinc deficiency, but zinc and iron are generally present in the same foods and there is also growing evidence for the public health importance of zinc deficiency in young children on a global basis. In populations that depend primarily on plant-based foods, biofortification of major food staples by traditional selective plant breeding procedures offers an attractive strategy for preventing iron and zinc deficiency in all age groups. Pearl millet, a major food staple in several areas of India, has both naturally relatively high concentrations of iron and zinc with demonstrated potential to increase these levels further with plant breeding. Before embarking on complex, costly efficacy, effectiveness studies of the potential health benefits of this biofortified grain, the objective of this project is to determine the extent to which iron and zinc absorption is increased in very young children who consume pearl millet as the primary grain and major food staple. This is a short term, cross-sectional double-blinded study in which the test or control pearl millet is fed for a total of 9 days. Primary outcome measures are the increases in iron and zinc absorption over a two-day period. Test meals will be labeled with a zinc stable isotope on Day 8 and an iron stable isotope on Days 8 and 9 during which days participants and their mothers will stay in their community health center. Food intake will be weighed and duplicate diets obtained. Percentage iron absorption will be determined from erythrocyte enrichment on Day 23. Fractional zinc absorption will be measured from urine enrichment with orally and intravenously administered zinc isotopes from timed samples collected on Days 12-15. Daily absorption of these minerals will be determined. Increases in intake and absorption of these minerals (mg/d) will be evaluated with respect to estimated dietary and physiologic requirements.

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment: 44 participants

Intervention Model: Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Prevention

Official Title: Zinc and Iron Bioavailability From Biofortified Pearl Millet

ARMs AND INTERVENTIONS

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: Pearl millet</td>
<td>Participants in the control arm consume non-biofortified pearl millet.</td>
</tr>
<tr>
<td>Experimental: Iron and zinc biofortified pearl millet</td>
<td>Participants in the experimental arm consume pearl millet which has been biofortified with iron and zinc.</td>
</tr>
<tr>
<td>Other: Pearl millet</td>
<td>Participants in the control arm consume pearl millet which has not been biofortified. The intervention is consumed for two days.</td>
</tr>
<tr>
<td>Other: Biofortified pearl millet</td>
<td>Participants in the experimental arm consume pearl millet biofortified with iron and zinc. The intervention is consumed for two days.</td>
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OUTCOME MEASURES

Primary Outcome Measures:
1. Absorption of iron from pearl millet [Time Frame: 2 days]
   Absorption of iron will be measured while the participants are eating pearl millet as their major food staple which will provide at least 50% energy and at least 75% iron, zinc and phytate of the diet. Fractional absorption of iron for two days will be measured by extrinsic labeling with stable isotopes of iron and measuring erythrocyte enrichment. Measurement of total iron in duplicate diets on test days will allow determination of quantity of this micronutrient absorbed (mg/d).

2. Absorption of zinc from pearl millet [Time Frame: 1 day]
   Absorption of zinc will be measured while the participants are eating pearl millet as their major food staple which will provide at least 50% energy and at least 75% iron, zinc and phytate of the diet. Fractional absorption of zinc for a day will be measured by extrinsic labeling with stable isotopes of zinc. Fractional absorption of zinc will be measured by a dual isotope tracer ratio technique. Measurement of total zinc in duplicate diets on test day will allow determination of quantity of this micronutrient absorbed (mg/d).
ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 36 Months (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
lives in one of the targeted communities apparently healthy 23 m of age [may need modification] Hemoglobin (Hb) > 8 g/dl ferritin ≤ 12mg/L

Exclusion Criteria:
Hemoglobin (Hb) 12 (even after correction for C-reactive protein (CRP)/ Alpha Glyco Protein (AGP) thalassemia birth weight < 2,500 g birth defect affecting growth and development chronic infection

CONTACTS AND LOCATIONS

Contacts

Locations
United States, Colorado
University of Colorado Denver
Aurora

India, Karnataka
JN Medical College (Human field studies)
Belgaum

Sponsors and Collaborators
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Jawaharlal Nehru Medical College
HarvestPlus
International Atomic Energy Agency

Investigator

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University of Colorado, Denver

MORE INFORMATION


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Biofortification
Pearl millet Iron absorption
Zinc absorption

Additional relevant MeSH terms:
Malnutrition
Nutrition Disorders