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Packaging nutrition and seasonal malaria chemoprevention in a community-based project: effects on programme coverage, child nutrition and health in Kano state, northern Nigeria

Submission date
22/01/2015

Recruitment status
No longer recruiting

Registration date
11/02/2015

Overall study status
Completed

Last Edited
07/03/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Malaria and malnutrition are two of the leading causes of illness and death in children under five years of age living in Nigeria. Research suggests that there is an association between malaria and nutrition, and that malnutrition can increase the severity of malaria; nearly 50% of all malaria deaths are attributable to malnutrition. Both malaria and malnutrition are highly seasonal. Across northern Nigeria, childhood morbidity and mortality from malaria spike during the rainy season, typically a 2–4 month period beginning in July or August of each year. Also, in northern Nigeria, the hunger season coincides with the rainy season, typically starting 1 month after the rains have begun. These several months are a time when children are extremely vulnerable to dying of causes that are completely preventable. SMC was endorsed by the World Health Organization in 2012 to reduce the burden of malaria and is the administration of a full treatment course of antimalarial medication to children living in areas of highly seasonal transmission. Likewise, LNS is a recommended treatment for malnutrition. The Clinton Health Access Initiative is implementing a study to take place in the Kano state (Nigeria), which has a population of nearly 2.5 million children under five. Twenty-five percent of under-five deaths (approximately 132,000 annually), are attributable to malaria and approximately 9% of the population have moderate malnutrition. The primary aim of this study is to determine whether the intervention coverage, and child nutrition and health outcomes are improved by packaging the delivery of LNS through the SMC campaign compared with the delivery of SMC alone.

Who can participate?
Children aged 6–24 months who reside in a study area and do not meet one of the exclusion criteria; coverage will be assessed in a wider group of children aged 3–59 months

What does the study involve?
The study involves the delivery of commodities to seven selected communities, once per month

for four months continuously beginning August through to November 2014. Control communities will receive SMC (sulfadoxine-pyrimethamine and amodiaquine [SP-AQ]). Intervention communities will receive SMC in addition to Plumpy'Doz, an LNS. Trained Community Drug Distributors (CDDs) will deliver the commodities door-to-door to households with eligible children. Three household surveys will also occur: the first in August before commodity distribution, the second after the final round of distribution in November, and the third in May, 6 months after the last distribution. These cross-sectional surveys will collect information on demographics, nutrition indicators, intervention coverage and adherence, and finally on long-term health impacts (height-for-age, weight-for-age) post-study. The project also includes a nested case-control component in which health-care workers in local health facilities will recruit and record information on incoming febrile patients for comparison of malaria outcomes.

What are the possible benefits and risks of participating?
While SP-AQ is safe and well tolerated when used in recommended doses and regimens, mild side effects may occur, of which the most common is vomiting associated with AQ ingestion. Severe side-effects including severe skin reactions and blood dyscrasias are rare. With Plumpy' Doz, there is a small chance of a child having an allergic reaction to the peanut component of the product. The allergy may cause reactions in the form of skin changes (hives, rashes and infections); body swelling; shortness of breath; and anaphylactic shock. Each child will be observed for 15 minutes after ingestion of either SP-AQ and/or Plumpy'Doz for signs of side effects. Any child who has an adverse reaction will have this recorded on a drug adverse reaction form and submitted to the National Agency for Food and Drug Administration and Control. Considerable published evidence supports that there is no risk of increased malaria incidence in this population due to iron supplementation through Plumpy'Doz at the dosage distributed through this study.

When is the study starting and how long is it expected to run for?
From August 2014 to May 2015

Where is the study run from?
Seven wards in Madobi, a local government area in Kano state (Nigeria)

Who is funding the study?
Children's Investment Fund Foundation (UK)

Who is the main contact?
Amy Mayberry

Contact information

Type(s)
Scientific

Contact name
Mr Arnaud Le Menach

Contact details
Malaria Research
Clinton Health Access Initiative
383 Dorchester Avenue Suite 400

Boston
United States of America
02127
+1-617-312-9213
alemenach@clintonhealthaccess.org

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Packaging lipid-based nutritional supplements together with seasonal malaria chemoprevention in a community-based pragmatic trial: effects on seasonal malaria chemoprevention coverage, child nutrition and health in Kano state, northern Nigeria

Acronym
SMAMP (Seasonal Malaria and Malnutrition Prevention)

Study objectives
In communities where seasonal malaria chemoprevention (SMC) is delivered in combination with lipid-based nutritional supplements (LNS) rather than by itself:
1. Hypothesis 1: coverage and adherence to SMC is higher
2. Hypothesis 2: child malnutrition is reduced
3. Hypothesis 3: the odds of uncomplicated or severe malaria are reduced (nested case-control study)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kano State Hospitals Management Board (Nigeria), 25/07/2014, Ref: HMB/GEN/488/vol. 1

Study design
Pragmatic community intervention trial with a nested case-control study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Malaria, malnutrition

Interventions
1. Once each month for four consecutive months, eligible children in the SMC-only group will receive co-blistered packs of sulfadoxine plus amodiaquine to be taken over 3 days (3 to <12

months dose pack contains one tablet of 262.5 mg sulfadoxine and three tablets of 75 mg each of amodiaquine; 12–59 months dose pack contains one tablet of 525 mg sulfadoxine plus three tablets of 150 mg each of amodiaquine).
2. Once each month for the same four consecutive months, eligible children in the SMC plus LNS intervention group will receive the same dose packs of sulfadoxine plus amodiaquine plus a 4 week supply of Plumpy'Doz lipid-based nutritional supplement (recommended dose 1.5 teaspoons three times per day for children 6–11 months old, three teaspoons three times per day for children 12–24 months).

Intervention Type
Mixed

Primary outcome(s)
1. SMC coverage (hypothesis 1): percentage of eligible children 3–59 months old who receive SMC during the distribution (in child months); will be measured at 3 months
2. SMC adherence (hypothesis 1): percentage of eligible children who complete the 3 day treatment course of SMC out of the total number of children who receive SMC during the final month of distribution; will be measured at 3 months
3. Nutritional status (hypothesis 2): mean height-for-age, weight-for-age and weight-for-length z-scores (WHO 2006 Growth Standards) in the SMC + LNS versus SMC-only communities; will be measured at baseline, 3 months and 9 months
4. Nested case-control study-specific clinical malaria incidence (hypothesis 3): difference in the odds of uncomplicated malaria illness (confirmed cases presenting at enrolled health facilities) in children 6–24 months old compared with matched cases and controls in the SMC only and SMC + LNS groups; will be measured after the recruitment period for the nested study ends on 31/12 /2014

Key secondary outcome(s))
1. SMC coverage in the group directly receiving LNS (6–24 months); will be measured at 3 months
2. Prevalence of malnutrition in SMC/LNC versus SMC-only communities (all using WHO growth standards); will be measured at baseline, 3 months and 9 months
2.1. Percentage of stunting (<-2 z-scores length-for-age) and percentage of severe stunting (<-3 z-scores)
2.2. Percentage of underweight (<-2 z-scores weight-for-age) and percentage of severe underweight(<-3 z-scores)
2.3. Percentage of wasting (<-2 z-scores weight-for-length) and percentage of severe wasting (<-3 z-scores) and percentage of severe acute malnutrition (severe wasting and/or mid-upper arm circumference <115 mm and/or oedema)
3. Malnutrition stratified by household food security status (an effect of the intervention may only be observed in the most food insecure households); will be measured at baseline, 3 months and 9 months
4. Severe malaria incidence: difference in the odds of hospital admissions for severe malaria per 1000 children 6–24 months old in the health facility catchment area comparing cases and controls in the SMC only and SMC + LNS groups; will be measured after the recruitment period for the nested study ends on 31/12/2014

Related studies will assess:
1. Cost-effectiveness; will be measured at 3 months
2. Reasons for coverage/non-coverage of SMC and LNS (quantitative, surveys, and qualitative,

focus group discussions); will be measured at 3 months
3. Community drug distributor experiences (qualitative, focus group discussions); will be measured at 3 months

Completion date
30/06/2015

Eligibility

Key inclusion criteria
SMC delivery:
1. Age 3–59 months old at the first distribution round
2. Residing in either intervention area

LNS delivery:
1. Age 6–24 months old at the first distribution round or 6 months of age before the distribution round 2, 3, or 4
2. Residing in the LNS-distribution intervention area
3. Parental informed consent

Nutrition indicators:
1. Aged 6–24 months old in both arms: SMC and SMC + LNS
2. SMC coverage will be analysed across the entire cohort of children who received SMC: 3–59 months old
3. LNS coverage will be analysed in children aged 6–24 months old in the SMC+LNS arm

Nested case-control study-specific (hypothesis 3) cases:
1. Presenting to an enrolled health facility between 27/08/2014 and 31/12//2014 with an axillary temperature of ≥37.5°C or a history of fever in the previous 48 hours and have parasitologically confirmed malaria by either rapid diagnostic test or microscopy
2. Age 6-24 months old at the first distribution round or 6 months old before distribution round 2, 3, or 4
3. Residing in an intervention area
4. Parental or guardian's informed consent (for parents or guardians who are between the ages of 12–18, they must provide informed assent and if their parent or guardian is nearby, this parent or guardian must also provide informed consent)
5. Meet eligibility requirements for SMC or SMC + LNS delivery depending on intervention area residence

Nested case-control study-specific (hypothesis 3) control:
1. Presenting to an enrolled health facility between 27/08/2014 and 31/12/2014 for febrile illness within the same week of the case and test negative for malaria by either rapid diagnostic test or microscopy
2. Residing in the same ward as the case
3. Age 6–24 months old at the first distribution round or 6 months old before distribution rounds 2, 3, or 4
4. Parental or guardian's informed consent (for parents or guardians who are between the ages of 12–18, they must provide informed assent and if their parent or guardian is nearby, this parent /guardian must also provide informed consent form)
5. Meet eligibility requirements for SMC or SMC + LNS delivery depending on intervention area residence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
59 months

Sex
All

Key exclusion criteria
SMC delivery:
1. Age < 3 or > 59 months old at the first distribution round
2. Severe acute illness
3. Unable to take oral medication
4. Confirmed malaria is defined as fever (body temperature of at least 37.5°C) or history of fever in the past 24 hours and parasitologically positive by rapid diagnostic test or microscopy; in the absence of rapid diagnostic test and microscopy diagnosis, malaria diagnosis should be based on clinical signs and symptoms
5. Human immunodeficiency virus (HIV)-positive and taking co-trimoxazole
6. Received a dose of sulfadoxine or pyrimethamine more recently than the past month
7. Allergic to sulfadoxine or pyrimethamine

LNS Delivery:
1. Age < 3 or > 24 months old at the first distribution round
2. Diagnosis of severe acute malnutrition as defined by mean upper arm circumference <11.5 cm
3. Allergy to peanuts

Nested case-control study-specific (hypothesis 3) case or control:
1. Age < 6 months old at the time of presentation to health facility
2. Age > 24 months at time of first distribution
3. Not residing in an intervention area

Date of first enrolment
01/06/2014

Date of final enrolment
03/08/2014

Locations

Countries of recruitment

Nigeria

Study participating centre
Community-based study
Madobi
Nigeria
-

Sponsor information

Organisation
Clinton Health Access Initiative

ROR
https://ror.org/013mr5k03

Funder(s)

Funder type
Charity

Funder Name
Children's Investment Fund Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/01/2019		Yes	No
Protocol (other)			07/03/2023	No	No