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Efficacy of community educational interventions in nutrition and WASH/Malaria in reducing anemia in children under five, in the municipality of Dande - Angola

Submission date
11/04/2016

Recruitment status
No longer recruiting

Registration date
06/09/2016

Overall study status
Completed

Last Edited
18/11/2021

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
The infant death rate in Angola is one of the highest in the world, and anemia is thought to be a major cause. Anemia is a condition in which there are not enough red blood cells or not enough of the component of blood that binds to oxygen (hemoglobin). It is thought that a major cause of anemia is insufficient iron intake from the diet (an essential part of hemoglobin). Eating a diet lacking in vitamins and minerals can lead to nutritional anaemia, however infectious diseases such as malaria (an infectious disease caused by a microscopic parasite which is spread from person to person by mosquitos) or schistosomiasis (an infection caused by a parasitic worm that lives in tropical and subtropical countries). The aim of this study is to find out whether consuming a more nutrient-rich diet by eating a more varied diet can help reduce rates of malaria better than reducing parasitic infections through the use of infection preventive practices.

Who can participate?
All children under 3 years old and the person who looks after them, who live in hamlets within Ucua, Mabubas and Caxito from the Dande municipality (Bengo province, Angola)

What does the study involve?
Hamlets are randomly allocated into one of three groups. Those in the first group take part in an education program about eating a more varied diet so that they have more vitamins and minerals in their diet. Those in the second group take part in an education program about good hygiene practices and how to prevent infections. Those in the third group are tested and treated for infectious diseases (including malaria and schistosomiasis). Participants in all groups receive bednets, soap and lye (used for cleaning). At the start of the study and then after 6 and 12 months, participants in all groups have blood tests to check whether they are suffering from anaemia.

What are the possible benefits and risks of participating?
Participating children benefit from health monitoring and treatment for infectious diseases. Participants found to have sickle cell disease (a type of anaemia involving unusual shaped red blood cells which do not function properly) receive free-of-charge medication. Travel expenses can be provided. Bednets, bleach and soap will be distributed to all children. Additionally, counseling will improve household health. There is a small risk that families may find the tests to be time consuming. In addition, there is a small risk of pain, bruising and infection during blood testing.

Where is the study run from?
The study is run from the Health Research Center of Angola and takes place in Ucua, Mabubas and Caxito from the Dande municipality (Bengo province, Angola)

When is the study starting and how long is it expected to run for?
November 2014 to September 2017

Who is funding the study?
1. Calouste Gulbenkian Foundation (Angola)
2. Banco de Fomento Angola (Angola)
3. Special Program for Research and Training in Tropical Diseases (Angola)
4. José Eduardo dos Santos Foundation (Angola)

Who is the main contact?
1. Miss Cláudia Fançony (public)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Anemia and its preventable etiologic agents in pre-school children from Bengo, Angola

Study objectives
Hypotheses
1. Educating mothers for adequate nutritional practices reduce anemia better than only deworming the children
2. Educating mothers for adequate Water, Sanitation and Hygiene practices reduce anemia better than only deworming the children
3. Educating mothers for adequate nutritional practices reduce anemia in children, better than educating mothers for adequate Water, Sanitation and Hygiene

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Ministry of Health of the Republic of Angola, 10/06/2015

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design

Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Anemia and its etiologic agents (malnutrition, micro-nutrient deficiency, malaria, schistosomiasis, STH, food security and socioeconomic conditions, etc).

Interventions
After the baseline evaluation (for which all eligible children will be invited to participate by a mobilization team in a census approach), the names of the hamlets (clusters) will be written on a paper and placed in a bag. The papers will then be successively removed from the bag, where the first pair removed will be allocated to the nutrition arm, the following pair to the WASH /malaria arm and the next to the control group, and so on successively until there is only one hamlet to be removed (which will be allocated to the nutrition group).

Group A: Nutrition educational intervention - Personalized (theoretical), home-based counseling of primary caretakers on infant and young children and community cooking practical classes.

Group B: WASH and malaria prevention educational intervention - Personalized (theoretical), home-based counseling of primary caretakers on adequate WASH and malaria preventive behaviors and community washing-hands practical classes

Group C: Control group - In this group, children will be screened and treated for malaria, schistosomiasis and STH at the baseline and in the follow up evaluations.

Children from all arms will be screened and treated for malaria, schistosomiasis and STH at the baseline and in the follow up evaluations (every six months).

Intervention Type
Behavioural

Primary outcome measure
Variation of hemoglobin levels during 12 months, measured in blood collected by venipuncture (by immunochromatography using an Hemocue 301+) at baseline, 6 and 12 months

Secondary outcome measures
1. Variation of anthropometric indices (weight and height, measured using platform/floor scales and infantometer/stadiometer, respectively) at baseline, 6 and 12 months
2. Micro-nutrient deficiency: ferritin, measured by turbidimetric/colorimetric techniques using an automated autoanalizer (BT1500) and folate, vitamin A and B12, measured by HPLC, in samples

collected at baseline, 6 and 12 months
3. Food diversity, measured by questionnaire completed by the mothers/caretakers, at baseline, 6 and 12 months

Overall study start date
10/11/2014

Completion date
15/09/2017

Eligibility

Key inclusion criteria
1. All children under 3 years old (and their primary caretakers)
2. Resident in hamlets with functional health posts within the communes of Ucua, Mabubas and Caxito from the Dande municipality (Bengo province, Angola)

Participant type(s)
Healthy volunteer

Age group
Child

Upper age limit
3 Years

Sex
Both

Target number of participants
There are 13 hamlets (clusters) with functional health posts registered within the area. Randomization may result in two arms with 4 clusters and one with 5 clusters. A density of 974 children in total are expected, however clusters are not expected to have the same density of eligible children.

Key exclusion criteria
1. Reported adverse reactions to albendazole and praziquantel
2. Failing the assessment and treatment at the baseline

Date of first enrolment
15/06/2015

Date of final enrolment
15/09/2016

Locations

Countries of recruitment
Angola

Study participating centre
Health Research Center of Angola
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Sponsor information

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Charity

Funder Name
Calouste Gulbenkian Foundation (Fundação Calouste Gulbenkian)

Funder Name
Banco de Fomento Angola (BFA)

Funder Name

Special Program for Research and Training in Tropical Diseases (TDR)

Funder Name
José Eduardo dos Santos Foundation (Fundação José Eduardo dos Santos)

Results and Publications

Publication and dissemination plan
1. Planned publication of the study protocol, a paper on the etiologic agents of anemia and another comparing the effect of nutritional and WASH educational interventions on the occurrence of anemia, compared to the control group
2. Planned presentation in international congresses of public health or tropical medicine, within 2016 and 2017

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/02/2019	18/06/2019	Yes	No
Results article		10/03/2021	18/11/2021	Yes	No