ISRCTN72928001 https://doi.org/10.1186/ISRCTN72928001

The contribution of health services in reducing chronic malnutrition in children infected by intestinal parasites in Bengo Province, Angola

Submission date
07/10/2016

Recruitment status
No longer recruiting

Registration date
07/04/2017

Overall study status
Completed

Last Edited
06/06/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
There are approximately 162 million children with chronic (long-term) moderate to severe malnutrition worldwide, mainly in the African and Asian continents (36% and 56%, respectively) where there is poor sanitation and hygiene conditions, and reduced access to health care. Chronic malnutrition has a major impact on the life of an individual. It can cause problems with a child's physical and cognitive (brain and psychological) development, performance in school, productivity and make them more vulnerable to long-term diseases as adults. Angola is currently the country with the highest death rate of children under five years of age and data from 2007 showed that malnutrition is an important public health problem, with 29% of these children suffering from it. Currently, the WHO has a clear strategy to combat soil-transmitted helminths infections (intestinal worms) through a deworming medication called albendazole. However it is important to treat other types of intestinal parasites as they can affect children's s physical and cognitive development. The aim of this study is to evaluate the contribution of health services, and in particular, deworming and specific treatment of infection by intestinal parasites at both the individual and household levels, to reducing chronic malnutrition in children between two and five years of age.

Who can participate?
Children aged 20-36 months who live in the Dande Health and Demographic Surveillance System study area and are infected with at least one intestinal parasite. Members of the children's household also take part in two of the four study groups.

What does the study involve?
After agreeing to be included in the study, children are randomly allocated to one of the four groups. Children in the first group are treated with two doses of albendazole at the start of the study and then as well as having their dietry intake assessed and being tested for anaemia (low red blood cell count or haemoglobin (the protein in blood that binds to oxygen) levels) and malaria at study visits taking place every four months for 24 months. In the second group, children and members of their household are treated with albendazole as well as undergoing the same assessments as the first group. In the third group, caregivers are given a container to

collect a stool sample from the child every four months so that it can be tested for the presence of instestinal parasites. They are then treated depending on what parasites are found, as well as undergoing the assessments. In the fourth group children and members of their household provide stool samples every four months for testing followed by receiving treatments and undergoing the assessments. In all groups, a questionnaire is used at all home visits in order to collect information about the children's health as well as being weighed and measured in order to assess their physical development.

What are the possible benefits and risks of participating?
Participants will benefit from individual and clinical assessment every four months, during two years. Where applicable, participants will benefit from proper treatment after being examined by a physician in the hospital without any financial cost. Risks of participating are related to pain that some participants may experience during the finger prick for blood collection. Participants may also experience side effects of the treatments applied, with abdominal or stomach pain being the most common. All participants have the right to drop out at anytime and to ask questions any time about anything they do not understand or simply want to know.

Where is the study run from?
Health Research Centre of Angola (Angola)

When is the study starting and how long is it expected to run for?
December 2013 to January 2017

Who is funding the study?
1. Foundation for Science and Technology Portugal (Portugal)
2. Calouste Gulbenkian Foundation (Portugal)
3. National Malaria Control Program, Ministry of Health, Angola (Angola)

Who is the main contact?
1. Mr Miguel Brito (scientific)
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Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The contribution of health services in reducing chronic malnutrition in children between two and five years of age: a community case study of infection by intestinal parasites in the province of Bengo, Angola

Acronym
SIP-BENGO (stunting&Intestinal parasites-Bengo)

Study objectives
The aim of this study is to investigate whether:
1. A strategy based on the treatment of the pathogenic intestinal parasites in children between 2 and 5 years of age has a greater contribution to the reduction of chronic malnutrition than deworming with albendazol
2. The contribution of deworming or treatment of intestinal parasites in reducing chronic malnutrition can be greater if applied at household level than at individual level

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Angolan Ministry of Health, 01/11/2013
2. Ethics Committee of the Instituto de Higiene e Medicina Tropical, Portugal 28/10/2014, ref: 13-2013-TD

Study design
Single-centre prospective four-arm randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
1. Chronic malnutrition
2. Infection by pathogenic intestinal parasites

Interventions
After being included in the study, caregivers will be asked about registration name, house name and age of all members of the household, as well as the neighbor of residence and contacts information. A study card of the child will be provided to caregivers with the schedule of all community follow-up (FU1-FU6) and information concerning assessment parameters of each follow-up, according to the arm of the study that the child was included, and the telephone contact of the coordinator of the study. As many streets do not have a name, to find the house of each participant a geographic coordinate provided by the HDSS will be used along with a point request near the house provided by caregivers. Each follow-up will be carried out by a team composed by a nurse, a clinical analysis technician and a motorist that moves by car to the house where the child lives and assessment will be done in the presence of the caregivers.

Arm 1:
Child: A single dose of albendazole 400mg will be provided to each child in the follow-up 1 and follow-up 4. Besides, nutritional assessment, anemia and malaria diagnosis will be performed during all follow-up visits.

Arm 2:
Child: A single dose of albendazole 400mg will be provided to each child included in the study in the follow-up 1 and follow-up 4. Besides, nutritional assessment, anemia and malaria diagnosis

will be performed during all follow-up visits.
Member of the household: A dose of albendazol will be provided to members of the household: 200mg single dose for those between 12 and 24 months and 400mg single dose for those above 24 months of age. Albendazol will not be provided to pregnant women and those that breastfeed their babies.

Arm 3:
Child: A specific container will be provided to caregivers to collect the stool samples of the child without any external stimulus. Once they collect the stool sample, caregivers will deliver the container in CISA's laboratory for microscopic detection of intestinal parasites. Management of positive results will be carried out by a physician in the Bengo General Hospital and according to the study protocol. A new specific container will be provided for stool collection 10 days after completing the recommended treatment to ensure the effectiveness of the treatment. Nutritional assessment, anemia and malaria diagnosis will be performed during all follow-up visits.

Arm 4:
Child: A specific container will be provided to caregivers to collect the stool samples of the child included in the study without any external stimulus. Once they collect the stool sample, caregivers will deliver the container in CISA´s laboratory for microscopic detection of pathogenic intestinal parasites (protozoa and helminths). Management of positive results will be carried out by a physician in the Bengo General Hospital and according to the study protocol. A new specific container will be provided for stool collection 10 days after completing the recommended treatment to ensure the effectiveness of the treatment. Nutritional assessment, anemia and malaria diagnosis will be performed during all follow-up visits.
Member of the household: A specific container will be also provided to each member of the household for stool sample collection and microscopic detection of pathogenic intestinal parasites (protozoa and helminths). Management of positive results will be carried out by a physician in the Bengo General Hospital and according to the study protocol. A new specific container will be provided for stool collection 10 days after completing the recommended treatment to ensure the effectiveness of the treatment.

Independently of the arm of the study, every child will be assessed for nutritional parameters, malaria diagnosis and anemia diagnosis. In case of a positive result for malaria, severia anemia (hemoglobin<7g/dl) and/or clinical signs of severe malnutrition (bilateral oedema or mid-upper arm circumference – MUAC < 11.5cm), the child will be assisted by a physician in the urgency unit of the Bengo General Hospital.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
1. Linear growth of children is assessed by mean change in height-for-age Zscores from baseline to 4, 8, 12, 16, 20 and 24 months of follow-up period
2. Improvement of weight for height is assessed by mean change in weight-for-height Zscores

from baseline to 4, 8, 12, 16, 20 and 24 months of follow-up period
3. Improvement of weight for age of children is assessed by mean change in weight-for-age Zscores from baseline to 4, 8, 12, 16, 20 and 24 months of follow-up period

Secondary outcome measures
1. Occurrence of infection by intestinal protozoa and helminths measured using stool sample analysis (direct examination with saline and iodine, a concentration method using Parasite Recovery System, kato-katz and kinyoun staining for coccidea diagnosis) from the baseline to 4, 8, 12, 16, 20 and 24 months of follow-up period
2. Occurrence of malaria measured using blood sample analysis from the baseline to 4, 8, 12, 16, 20 and 24 months of follow-up period
3. Improvement of anemia is assessed by mean change in haemoglobin (g/dl) from 4, 8, 12, 16, 20 and 24 months of follow-up period

Overall study start date
01/12/2013

Completion date
27/01/2017

Eligibility

Key inclusion criteria
Inclusion criteria of children:
1. Age between 20-36 months at the recruitment period
2. Residents in the Dande Health and Demographic Surveillance System study area
3. No history of antibiotherapy in the previous 10 days
4. Children infected with at least one pathogenic intestinal parasite
5. Informed consent signed by parents or primary caregivers

Inclusion criteria of household members (arm 2 and 4):
After permission of the caregiver for child to participate in the study, arms 2 and 4 preview the inclusion of all the members of the household. Written Informed consent is required.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
150 children between 20 and 24 months of age; 300 members of the households

Key exclusion criteria
Exclusion criteria of children:
1. Age under 20 months or above 36 months
2. Children whom parents or primary caregivers do not reside in the Dande Health – and

Demographic Surveillance System study area
3. Children with history of antibiotherapy or antiparasitic drug in the previous 10 days that can lead to false negatives in microscopic identification of pathogenic intestinal parasites
4. Children who are not infected with pathogenic intestinal parasites (protozoa and/or helminths)
5. Children whom parent or primary caregivers do not intend to participate in the study

Exclusion criteria for household members (arm 2 and 4):
1. Any person who does not live in the same household of the child included in the study
2. Household member who do not intend to participate in the study

Date of first enrolment
17/12/2013

Date of final enrolment
17/12/2014

Locations

Countries of recruitment
Angola

Study participating centre
Health Research Centre of Angola
Rua Direita do Caxito
Caxito, Província do Bengo
Angola
NA

Sponsor information

Organisation
Centro de Investigação em Saúde de Angola - CISA (Health Research Centre of Angola)

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Sponsor type
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Organisation
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Sponsor type
University/education

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Funder(s)

Funder type
Research organisation

Funder Name
Fundação para a Ciência e Tecnologia, Portugal (Foundation for Science and Technology Portugal)

Funder Name
Fundação Calouste Gulbenkian (Calouste Gulbenkian Foundation)

Funder Name
Programa de Controlo da Malária do Ministério da Saúde de Angola - MINSA (National Malaria Control Program, Ministry of Health, Angola)

Results and Publications

Publication and dissemination plan

The main results of the study will be published in in peer review journals and disseminated at national and international conferences.

Intention to publish date
01/01/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Miguel Brito (miguel.brito@cisacaxito.org) or Ms Carolina Gasparinho (carolina.gasparinho@cisacaxito.org)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/03/2021	07/12/2021	Yes	No
Results article		24/05/2022	06/06/2023	Yes	No