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Serum choline with linear growth failure in young children from rural Malawi

Submission date 26/04/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/04/2016	**Overall study status** Completed	
Last Edited 19/05/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Choline is an essential nutrient, required for many basic metabolic processes in the human body. Children in Africa are often stunted, or poorly grown. Nothing is known about the relationship between growth and the amount of choline in this population. This study will determine whether children who are poorly grown have lower or higher choline levels in their blood.

Who can participate?
Healthy children aged 6 months to 5 years resident in one of 5 rural Malawian villages

What does the study involve?
Participants have their length and weight measured, answer questions about their household living situation, and have their blood tested for choline and two choline breakdown products.

What are the possible benefits and risks of participating?
There is no benefit of participation for these children. The benefit to society is that something will be learned about choline and growth which may be used to help other children in the future. All of the data are made anonymous before analysis. There is only a minimal risk of discomfort to the participants, as they are receiving no interventions of any kind.

Where is the study run from?
University of Malawi (Malawi)

When is the study starting and how long is it expected to run for?
August 2008 to January 2013

Who is funding the study?
1. National Institutes of Health (USA)
2. Hickey Family Foundation (USA)
3. Children's Discovery Institute (USA)

Who is the main contact?
Dr Mark Manary

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Serum choline with linear growth failure in young children from rural Malawi

Study objectives
Low serum choline concentrations and higher betaine/choline and TMAO/choline ratios would be associated with linear growth failure in young children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. College of Medicine Research Ethics Committee of the University of Malawi, 07/03/2011, ref: P.05/08/669
2. Human Research Protection Office of Washington University in St. Louis, 31/03/2011, ref: 201103423
3. Johns Hopkins School of Medicine Institutional Review Board, 14/05/2015, ref: IRB00070244

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Childhood stunting

Interventions
At a single point in time this group of 325 children will have data regarding their height, weight and some basic demographic characteristics collected and a blood sample analyzed for 3 metabolites, choline, betaine and trimethylene N-oxide. These data will be analyzed to see if there is a relationship between the body size measurements and these metabolites in blood.

Added 15/09/2017:
The clinical aspects of the trial were completed as described in the original application. Subjects were recruited and participation was in accordance with initial registry information. Testing choline and choline metabolite levels were done as described. Upon testing the children's serum for choline and the emergence of interesting findings, it was decided that untargeted metabolite testing would be useful and informative. The original laboratory testing was targeted, the methods used for untargeted are the same, but this approach allows for discovery of metabolites that were not anticipated. Therefore the trial now includes targeted and untargeted testing of serum metabolites in the same population of Malawian children with varying degrees of environmental enteropathy.

Intervention Type
Other

Primary outcome measure
Serum choline, betaine and TMAO measured on the single day when the subject was encountered and tested. There is no follow-up.

Secondary outcome measures
Correlations between linear growth and choline, betaine and TMAO levels measured on the single day when the subject was encountered and tested. There is no follow-up.

Overall study start date
01/08/2008

Completion date
01/01/2013

Eligibility

Key inclusion criteria
Healthy children aged 6 months to 5 years resident in one of 5 rural Malawian villages

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Months

Upper age limit
5 Years

Sex
Both

Target number of participants
325

Total final enrolment
325

Key exclusion criteria
Chronically ill or acutely malnourished

Date of first enrolment
01/08/2008

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Malawi

Study participating centre
University of Malawi
College of Medicine
Malawi
Blantyre 3

Sponsor information

Organisation
Johns Hopkins University (USA)

Sponsor details
400 N. Broadway
Baltimore
United States of America
21287

Sponsor type
University/education

ROR
https://ror.org/00za53h95

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
Hickey Family Foundation

Funder Name

Children's Discovery Institute

Alternative Name(s)
CDI

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United States of America

Results and Publications

Publication and dissemination plan
The publication/dissemination plan is to complete the metabolomic analyses by July 2018 and publish these results in a peer reviewed journal by December 2018.

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
The subject level data for the metabolic analyses will be available as a supplement to the peer reviewed article. Until that time the subject level data will be held by the principal investigators.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016		Yes	No
Results article		25/10/2017	19/05/2023	Yes	No