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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
26/04/2016		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
27/04/2016		[X] Results		
Last Edited 19/05/2023	Condition category Other	[] Individual participant data		
13/03/2023	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

Dr Mark Manary

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

5 years

Sex

All

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

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Sponsor information

Organisation

Johns Hopkins University (USA)

ROR

https://ror.org/00za53h95

Funder(s)

Funder type

Government

Funder Name

National Institutes of Health

Alternative Name(s)

US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

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

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 adde	d Peer reviewed	? Patient-facing?
Results article	results	01/07/2016	Yes	No
Results article		25/10/2017 19/05/202	3 Yes	No