

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

<b>Submission date</b> 26/04/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## 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 added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2016		Yes	No
<a href="#">Results article</a>		25/10/2017	19/05/2023	Yes	No

