

The effects of lipid-based multiple micronutrients on the health of children in the developing world

Submission date 22/06/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/08/2017	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A randomised controlled trial to investigate the effects of physician prescribed lipid-based multiple micronutrients on the health of children presenting to a primary health care centre in The Gambia

Acronym

MMCT

Study objectives

Physician prescribed lipid-based nutritional supplement (LNS) with a comprehensive set of micronutrients will improve the health status of children self-presenting to a primary health care clinic.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Research Council (MRC) and the Gambian Government Ethics Committee, 27/03/2009, ref: SCC1135v2

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

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

Infant and child health status

Interventions

Randomised double-blind placebo-controlled trial of 25 g/d LNS (containing macronutrients and 23 micronutrients) under Good Clinical Practice (GCP) standards. Supplement will be administered by the carer. Compliance will be assessed by unannounced observations and

questionnaires. Subjects will be randomised into three groups:

1. 12 week LNS supplementation
2. 6 week LNS supplementation followed by 6 week placebo
3. 12 week placebo

Each child will be followed up for 1 year.

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lipid-based nutritional supplement (LNS)

Primary outcome measure

Health status as indicated by the frequency of self-referred clinic return attendances within 12 months from baseline specifying clinical diagnoses at each presentation to profile disease patterns and growth (weight, height/length, mid-upper arm circumference (MUAC)) at four points over 6 months.

Secondary outcome measures

Micronutrient status and standard haematology in a random subgroup of 300 subjects, measured at day 10 and at 12 weeks from start of supplementation.

Overall study start date

15/09/2009

Completion date

15/09/2011

Eligibility

Key inclusion criteria

Children aged 6 months - 5 years (either sex) from the West Kiang Region of The Gambia self-presenting to the clinic at MRC Keneba, West Kiang, The Gambia

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

5 Years

Sex

Both

Target number of participants

2250

Key exclusion criteria

1. Children from regions other than the West Kiang Region of The Gambia
2. Children known to be asthmatic or allergic to peanuts
3. Children known to be involved in another trial
4. Children with known haemoglobinopathies
5. Children with severe malnutrition (weight-for-height SD-score less than -3 or/and presence of oedema) (World Health Organization [WHO] 2000)
6. Children presenting to the clinic but called rather than self-referred (e.g. for DSS purposes and immunisations)

Date of first enrolment

15/09/2009

Date of final enrolment

15/09/2011

Locations**Countries of recruitment**

Gambia

Study participating centre

MRC Laboratories

Banjul

Gambia

-

Sponsor information**Organisation**

Medical Research Council (MRC) (UK)

Sponsor details

MRC London Centre

Stephenson House

158-160 North Gower Street

London

United Kingdom

NW1 2ND

-
andrew.prentice@lshtm.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

ROR

<https://ror.org/03x94j517>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) - International Nutrition Group (ING) Core Funding

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/08/2017		Yes	No