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Effects of spirulina supplement on children's growth and health

Submission date	Recruitment status	[_] Prospectively registered
20/11/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/12/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/12/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Spirulina (Arthrospira platensis, SP) is a microalga (microscopic plant that grows in water). It is a source of vitamins and other nutrients and has been considered as as food to combat malnutrition in low-income countries and to improve overall health by the United Nations World Food Conference of 1974. SP is generally recognized as safe (GRAS) for use as an ingredient in foods, at levels ranging from 0.5 to 3.0 g per serving. Very few research studies have been conducted in children. In Cambodia and other countries, SP is frequently provided to children from deprived settings by non-governmental organizations (NGOs), such as charities, operating in schools. SP is given to the children under the assumption that using low doses of SP daily (2 g) will improve the children’s growth and health due to SP’s positive nutritional content and positive impact on immunity. This strategy has not been investigated within a controlled study. This study aims to test the effects on children aged 5 to 6 years.

Who can participate?
Children aged 5 to 6 years attending preschool, with the informed oral consent of their parents /guardians and after a medical screening

What does the study involve?
The children were randomly and allocated Group 1 or Group 0. Group 1 received a 2-g teaspoon of SP powder daily and Group 0 received a 2-g teaspoon of placebo (dummy) powder for 8 weeks (Phase 1). After 8 weeks where the children did not receive SP or placebo, Group 1 received placebo and Group) received SP for 8 weeks (Phase 2). In addition to daily meal at school, children received daily one of the two regimens for a period of 2 months: either placebo or SP. The intake and tolerance of supplements were directly observed. Their blood was also taken (4 ml) by experienced nurses from the Cambodian Pasteur Institute at the school before the study, after the end of first phase and second phase. Sampling was not mandatory.

What are the possible benefits and risks of participating?
Using SP daily was expected to improve the children’s growth and health, and decrease the occurrence of anemia and other disease due to SP’s positive nutritional content and positive impact on immunity. Only mild and transient side-effects such as nausea and vomiting were expected.

Where is the study run from?
Antenna Technologies (Cambodia)

When is the study starting and how long is it expected to run for?
October 2014 to June 2015

Who is funding the study?
Antenna Cambodia

Who is the main contact?
Dr Hubert Barennes, barenneshub@yahoo.fr

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0000

Study information

Scientific Title
Evaluation of daily spirulina as a nutritional supplement in school children: a placebo-controlled randomized study

Study objectives
Daily spirulina supplementation can be beneficial on weight, growth, and hemoglobin level of young children from an impoverished setting in Cambodia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Ethics Committee for Health Research, Kingdom of Cambodia, 26/06/2015, ref: 260 NECHR

Study design
Single-centre double-blind placebo-controlled cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
School

Study type(s)
Prevention

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
Young children from an impoverished setting in Cambodia attending preschools

Interventions
All parents/guardians/caregivers were informed by the school manager and were provided an information file in Khmer. Children of those who provided oral consent to the study were enrolled. The participant information file and informed consent sheet provided the following details: the exact nature of the survey; what it would involve for the participant; the implications and constraints of the protocol; the known side-effects and risks involved in taking part in the study. It was clearly stated that the participant was free to withdraw from the survey at any time for any reason without prejudice to future care at PSE health services or PSE education and with no obligation to give the reason for withdrawal.

An information session in Khmer was conducted at PSE with PSE teachers and staff prior to enrolment to ensure that the parents understood the survey design, objectives and the study activities and that they understood the monitoring and blindness. They were given the opportunity to ask questions and receive answers. Teachers were able to provide additional information to parents/guardians/caregivers.

In case of side effects or disease, children were to be sent to the nursery and, if appropriate, to the PSE doctor. The supplementation was either to be discontinued or decreased and treatment to be provided according to PSE and Cambodian National health guidelines.

The protocol, informed consent form, and participant information sheet were submitted to and received agreement from the Cambodian Research Ethics Committee.

Children (4.9 years, 95%CI: 4.7–5.1; sex ratio F/M: 0.83) attending preschool cared by “Pour un sourire d’enfants” (PSE) a charity-supported training school, were randomly and double-blindly allocated (2 to 1) to SP (Group 1) or placebo (Group 0) 2 g daily for 8 weeks (Phase 1). After 8 weeks of wash-out period, participants were crossed over to the other group (Phase 2). Children were fed once daily at PSE and followed for 8 months.
Anthropometric measurements (weight, height, body mass index [BMI]) and selected hematological data (blood cell count, ferritin and C-reactive protein performed by Pasteur Institute, Cambodia) were assessed before intervention and at the end of each treatment period. Children participating to the 2 phases were pooled defining control and SP groups. Comparison between and within phases and groups were conducted.

Intervention Type
Supplement

Primary outcome measure
1. Change in nutritional status assessed using anthropometric measurements (weight, height, body mass index [BMI]) calculated using UNICEF tools assessed prior to the survey, then 2 months after the first and the second supplementation phases

Secondary outcome measures
1. Tolerability of supplements was directly observed by teachers. Events such as nausea, vomiting, allergic reaction, headache, and fever or other symptoms were recorded daily on a standardized pre-tested one sheet form by the teachers . Standard pre-tested sheets were prepared to make it easy for teachers to record daily any symptomatic health events, compliance or reactions to supplements. Data sheets were monitored daily during the first 2 weeks by a survey assistant, then twice weekly.
2. Occurrence of illness was recorded using the data sheets daily during the first 2 weeks by a survey assistant, then twice weekly. The occurrence of health events or diseases was systematically sought from teachers at each visit in the event of children dropping out.
3. Haematological data, including hemoglobin, blood cell count, C-reactive protein and ferritin, assessed before intervention and at the end of each treatment period

Overall study start date
01/10/2014

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Children aged 5 to 6 years
2. Attending preschool
3. Informed oral consent of their parents/guardians
4. Following a medical screening at PSE health center

Participant type(s)
Other

Age group

Child

Lower age limit
5 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
Sample size of 192 people. 10% additional children were added to account for any failures by withdrawal or recording of data. A total of 212 was needed, and rounded to 215

Key exclusion criteria
1. Known allergy to SP before the survey
2. Inability to attend school during the subsequent 8 months

Date of first enrolment
01/12/2014

Date of final enrolment
15/02/2015

Locations

Countries of recruitment
Cambodia

Study participating centre
Pour un Sourire d'Enfant (PSE) Schools
Village Trea, Sangkat Stueng Mean Chey, 402
Phnom Penh
Cambodia
12352

Sponsor information

Organisation
Antenna Technologies Cambodia

Sponsor details
135, St 95
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Cambodia
000

Sponsor type
Charity

Funder(s)

Funder type
Charity

Funder Name
Antenna Cambodia

Results and Publications

Publication and dissemination plan
A preliminary report is planned and then an international publication in a peer-reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication. The data are also available upon request from H Barennes barenneshub@yahoo.fr under stata or excel anonymous data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	primary and secondary outcome results	07/12/2022	12/12/2022	Yes	No