

Evaluation of the immune system in children aged 2 to 5 that receive yogurt enriched with beta glucans extracted from the fungus *Ganoderma lucidum*

Submission date 07/03/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/03/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/03/2016	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The immune system is a network of cells, tissues and organs which work to protect the body from infection. It takes time for the immune system to fully develop, and so children under five are more vulnerable to infections such as diarrhea and the common cold. Beta glucans are sugars found in bacteria, fungi and plants. For many years, they have been used to help boost the immune system in people whose natural defenses have been weakened due to disease or aggressive treatment, such as chemotherapy. It has been suggested that adding beta glucans to food could help to strengthen the immune system of young children. The aim of this study is to find out whether enriching yogurt with beta glucans from *Ganoderma lucidum* (a type of fungus) can help to strengthen the immune system of two to five year olds.

Who can participate?

Healthy children aged between two and five who are attached to the Childcare Foundation in Medellin Columbia).

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are given a normal yogurt to eat five days a week (Monday-Friday) for 12 weeks. Those in the second group are given a yogurt which contains added beta-glucan to eat five days a week (Monday-Friday) for 12 weeks. At the start of the study and then after 12 weeks, participants in both groups have a blood test, so that the levels of different immune cells can be measured in order to see whether their immune system is stronger.

What are the possible benefits and risks of participating?

There is a possibility that the participants that eat yogurts containing beta glucans could have a beneficial immune response. There are no notable risks involved with taking part in the study.

Where is the study run from?
Child Care Center, Lucila Jaramillo (Chile)

When is the study starting and how long is it expected to run for?
September 2015 to December 2015

Who is funding the study?
Colombian Institute for the Development of Science and Technology, Colciencias (Columbia)

Who is the main contact?
1. Dr Sergio Urrego (public)
2. Dr Edwin Higuera (scientific)
3. Dr Sandra Duque (scientific)
4. Dr Andrea Cano (scientific)

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Evaluation of changes on CD4+, CD8 T cells and NK, cells in children aged 2 to 5 during a 12 week intervention with a yogurt enriched with Ganoderma lucidum beta-glucans obtained biotechnologically: A double-blind randomized placebo controlled phase II trial

Study objectives

Consuming yogurt enriched with beta-glucans for 12 weeks increases the T lymphocytes sub-populations and NK cells in 2 to 5 year old children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics and Research Board of IPS Universitaria, University of Antioquia (Universidad de Antioquia), 26/08/2015, ref: 086

Study design

Phase II double-blind randomized placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Immune function

Interventions

Participants are randomly allocated to either intervention groups (Placebo or beta-glucans).

Placebo group: Children consume a standard yogurt once daily, five days a week (Monday-Friday) for 12 weeks.

Beta-glucan group: Children consume a yogurt enriched with beta-glucans extracted biotechnologically from Ganoderma lucidum once daily, five days a week (Monday-Friday) for 12 weeks.

Participants in both groups provide blood samples at baseline and 12 weeks for immunomodulation assessments.

Intervention Type

Supplement

Primary outcome measure

1. CD4+ and CD8+ T lymphocytes counts are measured using flow cytometry from blood samples at baseline and 12 weeks

2. NK cell counts are measured using flow cytometry (CD16+/CD56+) from blood samples at baseline and 12 weeks

Secondary outcome measures

1. Hemoleucogram is measured using flow cytometry at baseline and 12 weeks
2. Serum IgA is measured by immunoturbidimetry at baseline and 12 weeks
3. Nutritional and anthropometric measurements evaluated according to WHO guidelines and using WHO AnthroPlus software at baseline and 12 weeks
 - 3.1. Weight/Height index
 - 3.2. Height/Age index
 - 3.3. Weight/Age index
4. Th1/Th2 cytokines profile in serum is measured using Cytometric Bead Array (CBA) at baseline and 12 weeks

Overall study start date

04/09/2015

Completion date

11/12/2015

Eligibility

Key inclusion criteria

1. Children aged 2-5
2. Children attached to the Childcare Foundation - Medellin (Fundación de Atención a la Niñez (FAN) - Medellin)

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

2 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

160

Key exclusion criteria

1. Children whose parents refuse to sign and accept the informed consent
2. Children outside of the General and Social Health Care System of Colombia
3. Use of corticosteroids or any other medical or pharmaceutical intervention
4. Diabetes

Date of first enrolment

09/09/2015

Date of final enrolment

11/09/2015

Locations

Countries of recruitment

Colombia

Study participating centre**Child Care Center, Lucila Jaramillo**

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Sponsor information

Organisation

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Sponsor type

University/education

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Sponsor type

Industry

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Organisation

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Sponsor type

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Sponsor details

Sponsor type

Not defined

Website

<http://www.eafit.edu.co/Paginas/index.aspx>

ROR

<https://ror.org/03y3y9v44>

Funder(s)

Funder type

Research organisation

Funder Name

Colombian Institute for the Development of Science and Technology (Colciencias)

Results and Publications

Publication and dissemination plan

Planned publication of results in a peer reviewed journal.

Intention to publish date

01/07/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request