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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

Registration date
30/03/2016

Overall study status
Completed

Last Edited
29/03/2016

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 Higutia (scientific)
3. Dr Sandra Duque (scientific)
4. Dr Andrea Cano (scientific)

Contact information

Type(s)
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 ramdomized 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 citokines 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

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EAFIT University

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Sponsor type
University/education

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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