

Evaluation of the immune system in children aged 3 to 5 that receive a nutritional complement enriched with beta glucans extracted from the fungus *Ganoderma lucidum*

Submission date 21/04/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/05/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/05/2020	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 system of biological structures and processes that are in charge of protecting the human body from various harmful agents that can damage it. It protects the body from things that could make us ill or cause death, such as bacteria and viruses. The immune system takes time to mature, which means that children under five years of age are more susceptible to infections such as diarrhea and the common cold. One way to help children's immune systems fight off common infections is to give them food supplements that have extra ingredients designed to strengthen the immune system. A common ingredient used to boost food supplements is called beta-glucan. Beta-glucans come from plants and fungi (mushrooms), and they are well known to help support the immune system. The aim of this study is to see whether a food supplement containing beta-glucans derived from the mushroom *Ganoderma lucidum* can help boost the immune system of children aged 3 to 5 years old.

Who can participate?

Children attached to the Childcare Foundation - Medellin (Fundación de Atención a la Niñez (FAN) – Medellin)

What does the study involve?

Participants are given a nutritional supplement with added beta-glucan to take 5 days a week for 6 weeks. Blood tests are carried out at the start of the study, then again after 6 weeks, to see if the participants' immune system is stronger after taking the supplement.

What are the possible benefits and risks of participating?

The results of this study could lead to beta-glucan-enriched foods being used to improve the health of preschool children.

Where is the study run from?

Childcare Foundation - Medellin (Fundación de Atención a la Niñez (FAN) - Medellin) (Colombia)

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

Who is funding the study?
1. Progal-BT SAS (Colombia)
2. iNNpalsa (Colombia)

Who is the main contact?
1. Dr S Urrego (public)
surregor@progal-bt.com
2. Dr E Higueta (scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Edwin Higueta

Contact details
Calle 51 # 51-27
Corporación Universitaria Remington
Facultad de Ciencias de la Salud
Medellin
Colombia
050010374

Type(s)
Public

Contact name
Dr Sergio Urrego

Contact details
Calle 25 #65D 53
Medellín
Colombia
050024074
+54 4442060
surregor@progal-bt.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IN34-2014

Study information

Scientific Title

Evaluation of changes in T cells subpopulations and NK (natural killer) cells in children aged 3 to 5 during a 6 week intervention with a nutritional complement enriched with biotechnologically Ganoderma lucidum extracted beta glucans

Study objectives

A six weeks intervention with a nutritional complement enriched with beta glucans increases the T lymphocytes subpopulations and NK cells in 3 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), 26/11/2014, ref: 076.

Study design

Interventional open study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Improvement in the baseline levels of immune system components in children.

Interventions

Participants receive a nutritional supplement in a maltodextrin matrix, enriched with beta-glucans extracted biotechnologically from Ganoderma lucidum. The supplement is taken 5 days per week, over 6 weeks.

Intervention Type

Supplement

Primary outcome measure

Measured in blood sample at baseline then 6 weeks after intervention:

1. CD4+ and CD8+ T lymphocytes counts, measured by flow cytometry in whole blood collected.
2. NK cell counts, measured by flow cytometry (CD16+/CD56+).

Secondary outcome measures

1. Hemoleucogram measured by flow cytometry
2. Serum IgA measured by immunoturbidimetry
3. Nutritional and anthropometric measurements evaluated according to WHO guidelines and using WHO AnthroPlus software.
 - 3.1. Weight/Height index
 - 3.2. Height/Age index
 - 3.3. Weight/Age index

Overall study start date

01/07/2014

Completion date

27/01/2015

Eligibility**Key inclusion criteria**

1. Children aged 3-5
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

3 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

50

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

Date of first enrolment

16/12/2014

Date of final enrolment

04/01/2015

Locations

Countries of recruitment

Colombia

Study participating centre

Childcare Foundation - Medellin (Fundación de Atención a la Niñez (FAN) - Medellin)

Medellin

Colombia

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Sponsor information

Organisation

Progal-BT SAS

Sponsor details

Calle 25 65D-53

Medellin

Colombia

00000

(+574) 4442060

progalbt@progal-bt.com

Sponsor type

Industry

Website

www.progal-bt.com

ROR

<https://ror.org/037hmn502>

Funder(s)

Funder type

Industry

Funder Name

Progal-BT SAS (Colombia)

Funder Name

iNNpalsa (Colombia)

Results and Publications

Publication and dissemination plan

To be confirmed at a later date.

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

Available on request