

# Evaluation of the immune system in older adults that receive a nutritional complement enriched with beta glucans extracted from the fungus *Ganoderma lucidum*

<b>Submission date</b> 04/05/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/07/2015	<b>Condition category</b> 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. As people age, their immune systems weaken, meaning it becomes harder for older people to fight off infections such as the common cold. One way older adults can boost their immune system is to take food supplements that have extra ingredients designed to strengthen the immune system. A common ingredient used in 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 older adults.

### Who can participate?

Healthy adults aged 65-85 attached to the Care Center for Older Adults (Colombia).

### What does the study involve?

Participants are given a nutritional supplement with added beta-glucan to take 5 days a week for 12 weeks. Blood tests are carried out at the start of the study, then again after 12 weeks, to see if the participants' immune system is stronger after taking the supplement.

### What are the possible benefits and risks of participating?

Based on the results of previous studies, some possible benefits of participation include improvement of nutritional status evaluated by anthropometric measures, addition to daily diet, immune stimulation and potentiation, and cholesterol biosynthesis control. Risks associated with participation in this study include diarrhoea, vomiting and gastrointestinal discomfort during first days of intervention. Fullness and increased serum glucose (controlled by exclusion of diabetic and elevated serum glucose patients) is also a potential risk.

Where is the study run from?

Elderly Welfare Center, San Bernardo - Berta Arias Foundation, Botero (FUNDARIAS) (Centro de Bienestar del Anciano San Bernardo, Fundación Berta Arias de Botero (FUNDARIAS)) (Colombia)

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

July 2014 to March 2015

Who is funding the study?

1. Progal-BT SAS (Colombia)
2. iNNpulsa (Colombia)

Who is the main contact?

1. Dr S Urrego (public)  
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2. Dr E Higueta (scientific)

## Contact information

### Type(s)

Scientific

### Contact name

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Public

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

IN33-2014

## **Study information**

### **Scientific Title**

Evaluation of changes in T cells subpopulations and NK (natural killer) cells in older adults during a 12 week intervention with a nutritional complement enriched with biotechnologically Ganoderma lucidum extracted beta glucans

### **Study objectives**

A 12 week intervention with a nutritional complement enriched with beta glucans increases the T lymphocytes subpopulations and NK cells in older adults.

### **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)**

GP practice

### **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 older adults.

### **Interventions**

Participants receive a nutritional supplement in a maltodextrin and polydextrose matrix, enriched with beta glucans extracted biotechnologically from *Ganoderma lucidum* for a 12 week period.

## **Intervention Type**

Supplement

## **Primary outcome measure**

Measured in blood sample at baseline then 12 weeks after intervention:

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

## **Secondary outcome measures**

1. Haemoleucogram measured by flow cytometry
2. Serum IgA measured by immunoturbidimetry
3. Lipid profile measure by enzymatic colorimetric assay
4. Glucose levels measured by ultraviolet test
5. Nutritional and anthropometric measurements: body mass index (BMI)

## **Overall study start date**

01/07/2014

## **Completion date**

27/03/2015

# **Eligibility**

## **Key inclusion criteria**

Adults aged 65-85 attached to the Elderly Welfare Center, San Bernardo - Berta Arias Foundation, Botero (FUNDARIAS) (Centro de Bienestar al Anciano San Bernardo, Fundación Berta Arias de Botero (FUNDARIAS)).

## **Participant type(s)**

Healthy volunteer

## **Age group**

Senior

## **Sex**

Both

## **Target number of participants**

50

## **Key exclusion criteria**

1. Refuse to sign and accept the informed consent
2. Not within the General and Social Health Care System of Colombia
3. Use of corticosteroids or any other medical or pharmaceutical intervention
4. Anticoagulant treatment, stent, valve replacement, history of stroke
5. Diabetes

- 6. Mental impairments
- 7. Malnutrition or malnutrition risk

**Date of first enrolment**

16/12/2014

**Date of final enrolment**

05/03/2015

## Locations

**Countries of recruitment**

Colombia

**Study participating centre**

Elderly Welfare Center, San Bernardo - Berta Arias Foundation, Botero (FUNDARIAS) (Centro de Bienestar al Anciano San Bernardo, Fundación Berta Arias de Botero (FUNDARIAS))

Anexo 109 La Estrella

Antioquia

Colombia

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## Sponsor information

**Organisation**

Progal-BT SAS

**Sponsor details**

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**Sponsor type**

Industry

**Website**

<http://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 date, this study is in the phase of analysis of results and preparation of final manuscript. We hope to submit our manuscript in mid-June 2015.

## **Intention to publish date**

14/06/2015

## **Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Available on request