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Effect of a functional bread on blood pressure, glucose metabolism and endothelial function

Submission date
06/05/2013

Recruitment status
No longer recruiting

Registration date
20/05/2013

Overall study status
Completed

Last Edited
19/11/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hypertension (high blood pressure) is one of the main causes of cardiovascular disease, hospitalization and also a cause of death in developed countries. It has been extensively recognised that lifestyle change is the first step in the prevention (especially in those individuals with normal blood pressure) but also in the control of hypertension. Several changes in lifestyle such as quitting smoking, weight loss in overweight individuals, moderate alcohol consumption and following a healthy diet rich in vegetables and fruits, low in meat and processed food and moderate in low fat dairy products, and reducing salt intake are considered important to control hypertension. Gamma aminobutyric acid (GABA), a bioactive component is known for its role in regulation of blood pressure, neurotransmission (transmission of signals in brain cells), calming and diuretic (substance that promotes the production of urine which may decrease blood pressure) properties. Because of these and other beneficial properties, different food products enriched with GABA have been proposed as potential functional foods. Recently, our group has produced bread with lower glycemic index (low blood sugar levels) than traditional bread, fermented with bacteria that produce GABA and partially substituting sodium chloride (common salt) by potassium salts. This bread could have beneficial effects on blood pressure, insulin resistance and endothelial (thin layer of cells that line the interior surface of blood vessels which reduces friction of the flow of blood allowing the fluid to be pumped further) function. Therefore, the main aim of the present study is to assess the effect of bread reduced in sodium chloride and enriched with potassium salts and rich in GABA on blood pressure, insulin resistance, inflammation and endothelial function on subjects with prehypertension, or light or moderate hypertension.

Who can participate?
The study will include 30 men and women with pre-hypertension but who are not taking antihypertensive medication aged between 18 and 65 years.

What does the study involve?
All the participants will be randomly assigned to three interventions, each of four weeks duration:
1. Dietary recommendations + traditional bread
2. Dietary recommendations + bread reduced in sodium chloride and enriched with potassium

salts
3. Dietary recommendations + bread reduced in sodium chloride and enriched with potassium salts and containing 20 mg/100g of GABA.

What are the possible benefits and risks of participating?
The benefits for the participants are mainly that they will receive dietary counselling to follow a healthy diet by trained dietitians and also this study will help them to control the blood pressure. However, we cannot confirm that all participants will receive a direct benefit from the present study. But the study will provide further knowledge in relation to the consumption of different types of bread in the control of blood pressure, glucose and insulin metabolism and endothelial function. The main risk for the participant is that they could experience slight burning sensation during the blood test and also a hematoma (bruising) can appear. Rarely, they could suffer from sickness. However, the amount of blood sample taken is relatively small (65 ml).

Where is the study run from?
This study is conducted in the Hospital Sant Joan de Reus (Reus, Spain). The study is led by the Nutrition Unit, Faculty of Medicine and Health Science, IISPV, University Rovira i Virgili (Spain), and CIBERobn (P.I. Jordi Salas-Salvadó) with the collaboration of Vascular Medicine and Metabolism Unit, Lipids and Atherosclerosis Research Unit, Sant Joan University Hospital, IISPV, Spanish Biomedical Research Network in Diabetes and Associated Metabolic Disorders (CIBERDEM), Barcelona, Spain.

When is the study starting and how long is it expected to run for?
The study started in March 2013 and it is expected to finish in March 2014. The study will be recruiting participants from March 2013 until October 2013.

Who is funding the study?
The study is financed by Europastry, S.A.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
13-01-31/1PROJ3

Study information

Scientific Title
Effect of functional bread reduced in salt and fermented with dough containing lactobacillus brevis forming gamma-aminobutyric acid, on blood pressure, glucose metabolism and endothelial function

Acronym
PANTENS

Study objectives
Regular consumption of bread enriched with gamma-aminobutyric acid (GABA) and reduced in sodium chloride will have a short and medium term hypotensive effect compared to the consumption of traditional bread or bread reduced in sodium chloride.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sant Joan Hospital Ethical Committee, 31/01/2013, ref: 13-01-31/1proj3

Primary study design
Interventional

Study design
Randomised crossover double-blind clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pre-hypertension

Interventions
1. Healthy dietary recommendations + traditional bread
2. Healthy dietary recommendations + bread reduced in sodium chloride
3. Healthy dietary recommendations + bread reduced in sodium chloride fermented with Lactobacillus Brevis

120 g/day of bread in each intervention period.

Duration of intervention: 4 weeks for each of the three interventions.

Intervention Type
Other

Primary outcome(s)
Daily mean blood pressure measured by a 24 hour continuous register at baseline and at the end of each intervention period (after one month).

Key secondary outcome(s)
1. Blood pressure during activity and sleeping period
2. Blood pressure during the three hours after consuming the bread at morning.
3. Fasting glycemia, insulinemia and Homeostatic Measurement Assessment-Insulin Resistance (HOMA-IR)
4. Endothelial function and peripheral inflammation measured by biochemical markers.
5. Endothelial function measured by the Endo-PAT method
6. Adherence to the intervention
7. Tolerance and safety

Measured at baseline and at the end of each intervention period (after one month)

Completion date
06/03/2014

Eligibility

Key inclusion criteria
Patients (male and female) aged between 18 and 65 years with pre-hypertension but without antihypertensive medication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Severe hypertension (systolic blood pressure ≥ 160 mmHg, diastolic blood pressure ≥ 100 mmHg)
2. Type 2 diabetes
3. Body mass index (BMI) >35 kg/m^2
4. Target organ injuries attributed to hypertension
5. Inflammatory or infectious disease

6. Anti-inflammatory or antibiotic drugs
7. Alcoholism or drug abuse
8. Recent hypocaloric diet

Date of first enrolment
06/03/2013

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
Spain

Study participating centre
Universitat Rovira i Virgili
Reus
Spain
43201

Sponsor information

Organisation
Europastry (Spain)

ROR
https://ror.org/01rqhg698

Funder(s)

Funder type
Industry

Funder Name
Europastry (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015		Yes	No