

Probiotic cheese in hypocaloric diet

Submission date 29/10/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 15/11/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/11/2015	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Metabolic syndrome is a combination of diabetes, high blood pressure and obesity, which puts you at greater risk of heart disease, stroke and other conditions affecting the blood vessels. The aim of this study is to assess the effectiveness of a low-calorie diet supplemented with probiotic cheese in adult patients with obesity and high blood pressure.

Who can participate?

Obese people aged 30-69 with high blood pressure.

What does the study involve?

Participants are randomly allocated to one of two groups. One group consumes a low-calorie diet supplemented with 50g per day of probiotic cheese. The other group consumes a low-calorie diet supplemented with 50g per day of regular cheese. The study lasts for 3 weeks, and participants are asked to provide blood, urine and fecal samples to test the effects of the probiotic.

What are the possible benefits and risks of participating?

The study causes minimal inconveniences to participants. As blood samples are taken by an experienced nurse, the procedure is safe. However, there may be bruising and discomfort at the site of the blood test as with any blood test. The amounts of blood we are taking are small enough that they should not make you feel fatigue or cause anemia.

Where is the study run from?

The Clinic of the Institute of Nutrition, Russian Academy of Medical Sciences.

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

November 2010 to March 2011.

Who is funding the study?

Clinic of the Institute of Nutrition, Russian Academy of Medical Sciences.

Who is the main contact?

Prof Khayder Sharafetdinov
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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

53k on November 1, 2010

Study information

Scientific Title

Study of the efficiency of dietary inclusion of a probiotic product containing *Lactobacillus plantarum* Tensia™ DSM 21380 in obese patients with arterial hypertension

Study objectives

Probiotic cheese comprising *L. plantarum* TENSIA under the hypocaloric diet improves the host metabolic markers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institute of Nutrition Ethics Review Committee, Russian Academy of Medical Sciences, 17 November 2010, ref: 77

Primary study design

Interventional

Study design

Randomized blinded controlled parallel-designed two-armed intervention trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Metabolic syndrome with hypertension

Interventions

Standard treatment with hypocaloric diet with 50g of regular cheese for control group.

Standard treatment with hypocaloric diet with 50g/day probiotic cheese for test group.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Significant decrease of blood pressure
2. Significant decrease of body mass index (BMI)

Key secondary outcome(s)

Colonization of GI tract with *L. plantarum* Tensia

Completion date

31/03/2011

Eligibility**Key inclusion criteria**

1. Age 30-69 years
2. Diagnosis of metabolic syndrome characterized by obesity accompanied with arterial hypertension (>130/85 mm Hg)
3. Absence of decompensated chronic diseases needing intensive treatment
4. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. A history of gastrointestinal disease
2. Food allergy and acute infection
3. Use of any antimicrobial agent within the preceeding month
4. Pregnancy and breastfeeding
5. No wish to participate

Date of first enrolment

01/11/2010

Date of final enrolment

31/03/2011

Locations

Countries of recruitment

Russian Federation

Study participating centre

2/14 Ustinsky Proezd

Moscow

Russian Federation

109240

Sponsor information

Organisation

E-Piim (Estonia)

ROR

<https://ror.org/03by5ya49>

Funder(s)

Funder type

Industry

Funder Name

E-Piim (Estonia)

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	12/10/2013		Yes	No
Protocol article	protocol	01/08/2012		Yes	No