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Probiotic cheese in hypocaloric diet

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

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
Prof Khayder Sharafetdinov

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Committe, Russian Academy of Medical Sciences, 17 November 2010, ref: 77

Study design
Randomized blinded controlled parallel-designed two-armed intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Secondary outcome measures
Colonization of GI tract with L. plantarum Tensia

Overall study start date
01/11/2010

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 hypertonia (>130/85 mm Hg)
3. Absence of decompensated chronic diseases needing intensive treatment
4. Informed consent

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
40

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)

Sponsor details
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73301

Sponsor type
Industry

Website
http://www.epiim.ee/en

ROR
https://ror.org/03by5ya49

Funder(s)

Funder type
Industry

Funder Name
E-Piim (Estonia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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