Probiotic cheese in hypocaloric diet

Submission date 29/10/2012	Recruitment status No longer recruiting	 Prospectively registered [X] Protocol
Registration date 15/11/2012	Overall study status Completed	 [] Statistical analysis plan [X] 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 sharafandr@mail.ru

Contact information

Type(s) Scientific

Contact name Prof Khayder Sharafetdinov

Contact details

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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

Significant decrease of blood pressure
 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

 Age 30-69 years
 Diagnosis of metabolic syndrome characterized by obesity accompanied with arterial hypertonia (>130/85 mm Hg)
 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 c/o Mr Jaanus Murakas Pikk 16 Järva-Jaani Estonia 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