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Clinical effectiveness of a synbiotic

Submission date	Recruitment status	[_] Prospectively registered
12/10/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/10/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
This study is the first large study of probiotics in Kazakhstan and the first study on the new synbiotic yoghurt NAR. The uniqueness of this product lies in the fact that it consists of probiotic component strains isolated from a traditional Kazakh koumiss product. The aim of this study is to find out whether this synbiotic yoghurt can be used in the treatment of metabolic disorders such as obesity and diabetes.

Who can participate?
Patients with metabolic syndrome and healthy volunteers, aged 25 to 75

What does the study involve?
The participants are randomly allocated to take two cups (200 g) a day of a synbiotic yogurt or a placebo (without any prebiotic components) for 3 months. Body measurements, blood pressure, heart rate, blood and faeces samples, and stool consistency and frequency are assessed at the start of the study and at 90 days.

What are the possible benefits and risks of participating?
There are only minimal risks for patients associated with the stool sampling procedures.

Where is the study run from?
Medical Center under the Office of the Kazakh President (Kazakhstan)

When is the study starting and how long is it expected to run for?
January 2012 to January 2015

Who is funding the study?
Committee of Science of the Ministry of Science and Education of the Republic of Kazakhstan

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
311/2537 (IORG0006963)

Study information

Scientific Title
The effect of a new synbiotic yoghurt “NAR” (HƏP) in metabolic syndrome: a randomized, double-blind, placebo-controlled study

Acronym
NAR

Study objectives
The intake of this synbiotic yoghurt as an auxiliary in the treatment of metabolic disorders such as obesity, insulin resistance, diabetes mellitus and their comorbidities is highly effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Center for Life Sciences National Laboratory Astana Nazarbayev University, 04/04/2012, ref: 311/2537 (IORG0006963)

Study design
Randomized double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
Enrolled patients (either with metabolic syndrome or healthy) were randomly allocated to the synbiotic group or the placebo group, respectively. After analysis the groups were labeled as follows:
(A) Metabolic syndrome - synbiotic
(B) Metabolic syndrome – placebo
(C) Healthy – synbiotic
(D) Healthy – placebo

The participants will take two cups (200 g) a day for three months of either synbiotic yogurt or placebo. The participants of all groups received similar counseling for lifestyle modification regarding dietary habits.

Intervention Type
Other

Primary outcome measure
Measured at baseline and day 90:
1. Cardiovascular status (systolic and diastolic blood pressure, heart rate)
2. Stool consistency assessed according to the Bristol Stool Form Scale (BSS)
3. Stool frequency assessed on a 5-point scale
4. Blood samples collected for genomic studies
5. Stool samples collected for metagenomic studies
6. Body weight measured with a digital floor scale with 100 g accuracy, without shoes and with minimum clothing
7. Height measured to 1 mm accuracy with a non-elastic tape
8. Waist circumference measured with a non-elastic tape at a point midway between the lower border of the rib cage and the iliac crest at the end of normal expiration
9. Hip circumference measured with a non-elastic tape at the maximum girth of the buttocks
10. Blood glucose, glycosylated hemoglobin, total cholesterol, LDL, HDL, Triglycerides, C-reactive protein, hemoglobin, erythrocytes, leukocytes, platelets, and ESR, measured with

standard procedures using blood samples taken from the antecubital vein
11. Issues related to nutrition, general health, past illnesses, as well as marital status, parenthood and education, assessed using questionnaire. The questions related to nutrition included a comprehensive list of different kinds food and meals adapted according to common Kazakh dietary habits. These data were converted to macro- and micronutrient quantifications.

Secondary outcome measures
No secondary outcome measures

Overall study start date
03/01/2012

Completion date
31/01/2015

Eligibility

Key inclusion criteria
1. No history of the use of probiotics or antibiotics for 3 months
2. Blood pressure: = 130/90 mmHg
3. Raised fasting plasma glucose (FPG): >100 mg/dL (5.6 mmol/L), or previously diagnosed type 2 diabetes
4. Dyslipidemia TG: = 1.695 mmol/L; HDL-C = 0.9 mmol/L (male), = 1.0 mmol/L (female)
5. Central obesity: waist:hip ratio > 0.90 (male); > 0.85 (female), or body mass index > 30 kg/m2

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Acute illness or fever at the time of recruitment
2. Positive for HIV, hepatitis B or C, or for human papillomavirus (HPV)
3. Had anamnesis for surgery of the gastrointestinal tract, including any bowel resection
4. Pregnant or breastfeeding
5. Participants who had used the following medications during the last 6 months: antibiotics, antifungal, antiviral or antiparasitic drugs; corticosteroids; cytokines; commercial probiotics; or vaccines

Date of first enrolment
01/08/2014

Date of final enrolment

15/09/2014

Locations

Countries of recruitment
Kazakhstan

Study participating centre
Medical Center under the Office of the Kazakh President
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Sponsor information

Organisation
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Funder(s)

Funder type
Government

Funder Name

Committee of Science of the Ministry of Science and Education of the Republic of Kazakhstan

Results and Publications

Publication and dissemination plan
Planned submission to PLOS ONE and Nutrition journal (BMC).

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Almagul Kushugulova (akushugulova@nu.edu.kz).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	gut microbial analysis results	28/07/2018	25/11/2020	Yes	No