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Effectiveness of lactase enzyme in subjects with lactase non-persistence

Submission date	Recruitment status	[ ] Prospectively registered
05/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/05/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Yulia Khabarova

Contact details
Timme Str. 9-3-119
Archangelsk
Russian Federation
163060
+7 (0)921 487 3632
Yuliakaterina@rambler.ru

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of lactase enzyme in subjects with lactase non-persistence (LNP): a randomised double-blind placebo-controlled 2 x 2 cross-over study

Study objectives
There are differences in gastrointestinal symptoms after milk consumption between subjects with lactase non-persistence using lactase enzyme or placebo in a randomised double-blind setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Northern State Medical University approved on the 12th February 2010 (ref: 03/02)

Study design
Randomised double-blind placebo-controlled 2 x 2 cross-over single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Adult-type hypolactasia

Interventions
The study sample includes the group of students from Northern State Medical University. All subjects have previously undergone genotyping for detection of lactase persistent/non-persistent genotype. As a result about 150 subjects had C/C-13910 genotype (lactase non-persistent genotype, adult-type hypolactasia). Medical students aged 17 to 26 years in quantity up to 120 subjects will be taken into this randomised double-blind placebo-controlled 2 x 2 cross-over study to estimate the effectiveness of lactase enzyme. All of them will be asked for written informed consent.

The explanation about the aim and (order) practical conduction of study will be given orally before the start. Moreover students will get a booklet with information about lactose non-

persistence and lactose-containing products. All participants will be asked to avoid lactose-containing products 2 days before study and 3 hours after the intervention. The study will start in the morning.

Every subject has to fast overnight before the intervention. 500 ml of milk together with 2 capsules (lactase enzyme or placebo) will be given to the subjects in a randomised manner. After that every person will have to fill in a table with possible gastrointestinal symptoms and hourly mark a number according to the scale of severity. Subjects are not allowed to consume any food during three hours after the milk load. After three hours, all subjects will be provided the same lunch.

After a wash-out period of 1 week, students will come back, and the second period of the study will be conducted similarly to the first one (500 ml of milk + lactase enzyme or placebo). The estimation of symptom severity and fasting before and after the intervention will be done similarly as during the first intervention period.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lactase enzyme

Primary outcome measure
Five symptoms connected to lactose intolerance will be estimated by using the scale of severity where 1 is the minimal severity and 10 is maximum. Zero means no symptom. Subjects will fill in the table of severity of symptoms before intervention, 1 hour, 2 hours and 3 hours after the intervention and the rest of day after lunch.

Secondary outcome measures
No secondary outcome measures

Overall study start date
06/04/2010

Completion date
30/04/2010

Eligibility

Key inclusion criteria
1. Students from medical university with previously confirmed lactase non-persistent genotype (C/C-13910), aged 17 - 26 years, either sex
2. Students are included into study regardless of previous diseases, gastrointestinal symptoms, either connected or not with milk intake
3. All subjects will be fasting overnight before study and will be asked to avoid lactose content

products 2 days before the study
4. Subjects will be asked to avoid lactose-containing food during 3 hours after the milk load with lactase enzyme or placebo

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
92

Key exclusion criteria
1. Inability or refusal to sign informed consent
2. Students younger or older than age of study group

Date of first enrolment
06/04/2010

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
Russian Federation

Study participating centre
Timme Str. 9-3-119
Archangelsk
Russian Federation
163060

Sponsor information

Organisation
Oy Verman Ab (Finland)

Sponsor details
PO Box 146
Kerava

Finland
FI-04201

Sponsor type
Industry

Website
http://www.verman.fi

ROR
https://ror.org/0116f3t39

Funder(s)

Funder type
Industry

Funder Name
Oy Verman Ab (Finland)

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