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Investigation of whey-based dairy products

Submission date	Recruitment status	[_] Prospectively registered
05/11/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/11/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/02/2022	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Prostate complaints, especially those associated with urination, are very common and reduce the quality of life of many men. Every non-pharmaceutical possibility (without the use of medication) to relieve urinary difficulties of men would be valued and it would be the best if a novel food product would have such effect. Thus there is a need for production and use of reliable, test-proven food products and dietary supplements with healthy properties. The use of lactic acid bacteria has been described beneficial for the treatment of urogenital infections, including prostate infection.
The initial studies showed that whey-based lactobacilli-treated special dairy products may have beneficial effect on men with moderate urination problems

Who can participate?
Men aged 45-75 yrs with moderate urination problems

What does the study involve?
Participants are randomly allocated to active or control group
Active group receives fermented whey-based drink (200g per day) for 4 weeks
Control group receives whey-based drink (200g per day) for 4 weeks

What are the possible benefits and risks of participating?
Study participants get assessment of their health status and if necessary, free consultation of a nutritionist and/or a specialist. This health assessment will provide more precise overall health status of participant.
The study causes minimal inconveniences to participants. As blood samples are taken by 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?
In andrology clinic in Tartu, Estonia

When is the study starting and how long is it expected to run for?
This study is starting in October 2012, it is expected to complete in January 2014.

Who is funding the study?
The study is funded by the grant from European Union (EU) Structural Funds

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
215/T-3

Study information

Scientific Title
Efficacy of Whey-Based Dairy Products in the case of the Men With moderate Urination Problems (IPSS score < 19)

Acronym
WBDPMWUP

Study objectives
Whey-based lactobacilli-treated special whey products may have effect on men with moderate urination problems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the University of Tartu (UT REC), June, 14, 2012, ref:215/T-3

Study design
Randomized double-blind placebo controlled two armed study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moderate urination problems

Interventions
Participants randomised to active or control group
1. Active intervention: fermented whey-based drink (200g per day)
2. Control: whey-based drink (200g per day)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Significant improvement of urinary problems of men with moderate urination problems (IPSS score 8-19)

Key secondary outcome(s))
Improvement / maintenance of clinical, biochemical, immunological and metabolic profile of men with moderate urination problems (IPSS score 8-19)

Completion date
26/01/2014

Eligibility

Key inclusion criteria
1. A written informed consent#
2. Men (45-75 yrs of age) with moderate urination problems (IPSS score 8-19; International Prostate Symptome Score) having next indices:
2.1. Prostate-specific antigen (PSA) <10 ng/mL
2.2. Urinary flow rate 5-15 mL/s
2.3. Prostate volume <80 mL
2.4. Residue urine (measured abdominally) <300 mL

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Tumors of urinary tract, prostata, genital tract
2. Suffer from acute strong cholics of the urinary(genital) tract
3. Radio- or chemotherapy of pelvis
4. Prostate operation
5. Using α1- adrenoblocators within last two weeks
6. Using 5 α-reductase inhibitors within last 3 months
7. History of alcohol of drug abuse

Date of first enrolment
31/10/2012

Date of final enrolment
26/01/2014

Locations

Countries of recruitment
Estonia

Study participating centre
Ravila str 19
Tartu
Estonia
50411

Sponsor information

Organisation
BioCC OÜ

Funder(s)

Funder type
Government

Funder Name
European Union (EU) Structural Funds ref: EU30002

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	23/02/2018	21/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes