

# Investigation of whey-based dairy products

<b>Submission date</b> 05/11/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/02/2022	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## 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?

Tiiu Kullisaar, PhD  
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## Contact information

### Type(s)

Scientific

### Contact name

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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 Symptom 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  $\alpha$ 1- adrenoblocators within last two weeks
6. Using 5  $\alpha$ -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?
<a href="#">Results article</a>	results	23/02/2018	21/01/2019	Yes	No