

# Serenoa repens, cucurbita pepo, lycopene and selenium as an adjunct to the treatment of chronic bacterial prostatitis with antibiotics

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<b>Registration date</b> 05/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/10/2017	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chronic bacterial prostatitis is a bacterial infection of the prostate (a small gland located directly below the bladder in men). The aim of this study is to assess whether a capsule containing serenoa repens, cucurbita pepo, lycopene and selenium, used alongside antibiotics, can relieve the symptoms of chronic bacterial prostatitis and prevent reinfection.

### Who can participate?

Men with chronic bacterial prostatitis

### What does the study involve?

Participants are randomly allocated to one of two groups. Both groups receive antibiotic treatment for 15 days as a part of the regular treatment of chronic bacterial prostatitis. One group receives 6 months of treatment with one capsule per day of the study supplement (serenoa repens, cucurbita pepo, lycopene and selenium), while the other group receives one capsule per day for the same time period containing corn oil (placebo). The two groups complete symptom questionnaires and undergo urine flow tests and ultrasound scans at the start of the study and 1, 3, 6 and 12 months later.

### What are the possible benefits and risks of participating?

The benefits include relief of the patients from chronic prostatitis symptoms and the improvement of their quality of life. There are no risks involved in participating in the study.

### Where is the study run from?

Tzaneio Prefecture General Hospital (Greece)

### When is the study starting and how long is it expected to run for?

September 2016 to June 2019

### Who is funding the study?

Synapse Hellenic Pharmaceuticals & Services (Greece)

Who is the main contact?

1. Benjamin Polatidis (public)
2. Konstantinos Stamatiou (scientific)

## Contact information

### Type(s)

Public

### Contact name

Mr Benjamin Polatidis

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### Type(s)

Scientific

### Contact name

Mr Konstantinos Stamatiou

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SRCLS-CT-2016

## Study information

### Scientific Title

Serenoa repens, cucurbita pepo, lycopene and selenium as an adjunct to the treatment of chronic bacterial prostatitis with antibiotics: a placebo-controlled, double-blind, randomized clinical trial

Study objectives

The study hypothesis is that:

1. During the 2nd and the 3rd patients' visits there will be a statistically significant difference in the overall NIH-CPSI Questionnaire Score favouring the Group A (serenoa repens, cucurbita pepo, lycopene and selenium group) in comparison with Group B (placebo - corn oil group)
2. In all four visits (1, 3, 6 and 12 months), there will be a statistically significant difference in the IPSS Questionnaire Score favouring the Group A (serenoa repens, cucurbita pepo, lycopene and selenium group) in comparison with Group B (placebo - corn oil group), when comparing the subgroup of patients rated as moderate symptoms during initial visit (Initial IPSS : 8-19)
3. After 12 months, there will be lower rates of bacterial reinfection symptoms in Group A (serenoa repens, lycopene and selenium) in comparison with Group B (placebo group)

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Institutional Review Board of Tzaneio Prefecture General Hospital, 13/12/2016

### **Study design**

Single-centre double-blind placebo-controlled study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **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**

Chronic bacterial prostatitis and lower urinary tract symptom (LUTS)

### **Interventions**

Participants are randomised into two groups (block randomisation, computer generated algorithm).

Both groups receive antibiotic treatment for 15 days as a part of their regular treatment of chronic bacterial prostatitis. One group will receive 6 months of treatment with one capsule per day of the product (Serenoa Repens, Cucurbita Pepo, Lycopene & Selenium), while the other group will receive one capsule per day for the same time period containing corn oil (placebo).

The study will compare the groups' scores in the two basic questionnaires National Institute of Health's Chronic Prostatitis Symptom Index (NIH-CPSI) and International Prostate Symptom Score (IPSS), as well as changes in the clinical measurements Qmax, residual volume and prostate volume observed 1, 3, 6 and 12 months after the initial visit.

### **Intervention Type**

Supplement

### **Primary outcome measure**

1. Prostatitis symptoms assessed using the National Institute of Health's Chronic Prostatitis Symptom Index (NIH-CPSI) and International Prostate Symptom Score (IPSS) at baseline, 1, 3, 6 and 12 months
2. Qmax measured using specific uroflowmetry techniques at baseline, 3, 6 and 12 months
3. Residual volume after urination and prostate volume measured by the urologist using ultrasound at baseline, 3, 6 and 12 months

### **Secondary outcome measures**

Bacterial reinfection, assessed using Meares - Stamey Test and microbiological testing at baseline, 3, 6 and 12 months

### **Overall study start date**

01/09/2016

### **Completion date**

30/06/2019

## **Eligibility**

### **Key inclusion criteria**

Adult patients with chronic bacterial prostatitis

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Male

### **Target number of participants**

128

### **Key exclusion criteria**

1. Patients who are immediately diagnosed during their visit with acute bacterial prostatitis (NIH Category I)
2. Patients who receive treatment with an  $\alpha$ -blocker (Terazosin, Doxazosin, Tamsulosin, Alfuzosin)
3. Patients who have been under treatment with antibiotics through the last 6 months

4. Patients who are under treatment with immunosuppressant drugs
5. Patients who are under treatment with drugs containing cortisone
6. Patients who are allergic to corn or cucurbita pepo
7. Patients who suffer from diabetes mellitus
8. Patients who had a history of urethral stricture or neurogenic bladder

**Date of first enrolment**

01/11/2017

**Date of final enrolment**

31/12/2017

## **Locations**

**Countries of recruitment**

Greece

**Study participating centre**

Tzaneio Prefecture General Hospital

Leoforos Afentouli ke Zanni

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## **Sponsor information**

**Organisation**

Synapse Hellenic Pharmaceuticals & Services

**Sponsor details**

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**Sponsor type**

Industry

**Website**

[www.synapse.com.gr](http://www.synapse.com.gr)

**ROR**

<https://ror.org/01vx59p26>

# Funder(s)

## Funder type

Industry

## Funder Name

Synapse Hellenic Pharmaceuticals & Services

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal by September 2019.

## Intention to publish date

01/09/2019

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Theodosios Theodosiou from StatNous, the company that will take over the whole statistical processing of the data (theodosiou@statnous.com). The data is expected to become available 3 months after the last patients visit. August 2019 is an approximate time expected. Consent from participants is obtained through the ICF form. No specific criteria have been set on who would be given access to the data, but after the work is published the data will be shared to anyone seriously interested upon request.

## IPD sharing plan summary

Available on request