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

Submission date	Recruitment status	[X] Prospectively registered
04/10/2017	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
05/10/2017	Completed	Results
Last Edited	Condition category	Individual participant data
05/10/2017	Urological and Genital Diseases	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

Contact details

Egnatias 117 Thessaloniki Greece 54635

Type(s)

Scientific

Contact name

Mr Konstantinos Stamatiou

Contact details

Leoforos Afentouli ke Zanni Pireas, Greece Greece 185 36

Additional identifiers

Protocol serial number

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

Study type(s)

Quality of life

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 Healths' 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(s)

- 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

Key secondary outcome(s))

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

Completion date

30/06/2019

Eligibility

Key inclusion criteria

Adult patients with chronic bacterial prostatitis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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 a-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. Patents who are allergic to corn or cucurbita pepo
- 7. Patents 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

Sponsor information

Organisation

Synapse Hellenic Pharmaceuticals & Services

ROR

https://ror.org/01vx59p26

Funder(s)

Funder type

Industry

Funder Name

Synapse Hellenic Pharmaceuticals & Services

Results and Publications

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant

Participant information sheet 11/11/2025 11/11/2025 No

Yes