ISRCTN10248199 https://doi.org/10.1186/ISRCTN10248199

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

Submission date
04/10/2017

Recruitment status
No longer recruiting

Registration date
05/10/2017

Overall study status
Completed

Last Edited
05/10/2017

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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 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 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 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
Pireas
Greece
18536

Sponsor information

Organisation
Synapse Hellenic Pharmaceuticals & Services

Sponsor details
Egnatias 117
Thessaloniki
Greece
54635
+30 (0)2310217876
info@synapse.com.gr

Sponsor type
Industry

Website
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