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Serenoa repens, lycopene and selenium vs. tamsulosin for the treatment of lower urinary tract symptoms (LUTS)/ Benign prostatic hyperplasia (BPH)

Submission date
06/11/2013

Recruitment status
No longer recruiting

Registration date
11/12/2013

Overall study status
Completed

Last Edited
25/05/2017

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Lower urinary tract symptoms can greatly reduce the quality of life in men and cause issues with urinating. They can be a sign of a benign prostatic hyperplasic (BPH) or an enlarged prostate. Even today, the exact reasons underlying the development and progression of LUTS / BPH have not been fully understood. Recent studies have shown that chronic inflammation (swelling) represents a crucial part in BPH, probably determining the hyperplasia (enlargement) of prostate cells. The inflammatory cells in fact, produce growth factors such as VEGF or TGF- β , which can support the fibromuscular growth in BPH. This is treated by using medication that block the growth such as alpha-blockers and 5-alpha reductase inhibitors or combination therapy have been used to relief symptoms and to prevent complications. Other studies have demonstrated the significant benefits of the combination therapy if compared with individual single therapies. However, despite the improvement in symptoms, side effects (erectile dysfunction, ejaculatory disorders, loss of libido) may limit adherence (sticking to) to treatment. For these reasons, some phytotherapics (using herbs for treatment), like the lipid extract (LE) of Serenoa repens (SeR) , selenium (Se) and lycopene (Ly) are currently used with the aim of improving symptoms and to limit the possible adverse effects. The aim of this study is to evaluate the efficacy and tolerability of a combination therapy of phytotherapies versus the single therapies in patients with LUTS/BPH.

Who can participate?
Adult men aged between 55 to 80 years old who have LUTS/BPH

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive Ser 320 mg, Ly and Se (Profluss ®) 1 tablet per day for 1 year. Those in the second group receive tamsulosin 0.4 mg 1 tablet a day for 1 year. Those in the last group receive Ser 320 mg , Ly and Se (Profluss ®) 1 tablet per day for 1 year + tamsulosin 0.4 mg 1 tablet per day for 1 year. Participants are assessed for IPSS, IPSS quality of life, IIEF-5, Qmax, post-void residual and

ejaculation.
What are the possible benefits and risks of participating?
Participants may benefit from a reduction of IPSS and PVR and increase in Qmax and quality of life. Risks would

Where is the study run from?
Via Santa Sofia 78 (Italy)

When is the study starting and how long is it expected to run for?
March 2011 to March 2012

Who is funding the study?
Konpharma (Italy)

Who is the main contact?
Professor Giuseppe Morgia

Contact information

Type(s)
Scientific

Contact name
Prof Giuseppe Morgia

Contact details
Via Santa Sofia 78
Catania
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95100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
618/12

Study information

Scientific Title
Serenoa repens, lycopene and selenium vs. tamsulosin for the treatment of (LUTS)/ (BPH): An Italian multicenter comparative randomized study between single or combination therapy

Acronym
PROCOMB

Study objectives
To evaluate the efficacy and tolerability of the combination therapy between SeR, Ly and Se (Profluss ®) + tamsulosin versus the individual monotherapies with Ser, Ly and Se (Profluss ®) or tamsulosin in patients with LUTS/BPH.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Polyclinic Hospital, University of Catania, 09 Oct 2011, ref: Identification Number 618

Study design
Randomized double-blinded multicenter study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Benign prostatic hyperplasia (BPH) / lower urinary tract symptoms (LUTS)

Interventions
Participants were randomized with a 1:1:1 ratio into three treatment arms each consisting of 75 patients: group A (Ser 320 mg, Ly and Se (Profluss ®) 1 tablet per day for 1 year), group B (tamsulosin 0.4 mg 1 tablet a day for 1 year), group C (Ser 320 mg , Ly and Se (Profluss ®) 1 tablet per day for 1 year + tamsulosin 0.4 mg 1 tablet per day for 1 year.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Serenoa repens, lycopene and selenium, tamsulosin

Primary outcome measure

Reduction of IPSS (≥ 3 points from baseline), a percentage reduction of IPSS (IPSS%) ≥ 25%, increase of Qmax (≥ 30% from the baseline) and the reduction of PVR in patients treated with SeR, Ly and Se (Profluss ®) + tamsulosin compared to those treated with SeR, Ly and Se (Profluss®) or tamsulosin monotherapies after 1 year

Secondary outcome measures
Secondary endpoints of the study were considered the change in erectile function (assessed by the International Index of Erectile Function-5 questionnaire), prostate volume, serum PSA and QoL at 1 year

Overall study start date
01/03/2011

Completion date
01/03/2012

Eligibility

Key inclusion criteria
1. Age between 55 and 80 years old
2. Digital rectal examination negative for prostate cancer
3. Prostate-specific antigen (PSA) ≥ 4 ng / ml, International Prostate Symptom Score (IPSS) ≥ 12, prostate volume ≤ 60 cc (assessed by suprapubic ultrasound), Qmax ≤ 15 ml / s, post -void residual urine <150 ml.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
225

Key exclusion criteria
1. Prostate cancer, previous bladder cancer, diabetes mellitus, neurogenic disorders, severe liver disease, history of orthostatic hypotension or syncope, symptomatic urinary tract infection
2.Anti-androgens, antidepressants (neuroleptics, anticholinergics) therapy, recent treatment with an α blocker (within 1 month) or phytotherapy including saw palmetto extract (within 3 months), previous medical therapy with 5-ARI or surgical treatment for LUTS/BPH
3. Patients with catheter or with an episode of acute retention of urine in the last 4 weeks.

Date of first enrolment
01/03/2011

Date of final enrolment

01/03/2012

Locations

Countries of recruitment
Italy

Study participating centre
Via Santa Sofia 78
Catania
Italy
95100

Sponsor information

Organisation
Konpharma (Italy)

Sponsor details
via Pietro Della Valle, 1
Roma
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Sponsor type
Industry

ROR
https://ror.org/052hty126

Funder(s)

Funder type
Industry

Funder Name
Konpharma (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/11/2014		Yes	No