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Sprite study

Submission date	Recruitment status	[X] Prospectively registered
23/04/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/05/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2019	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Benign prostatic hyperplasia (BPH) (prostate enlargement) and lower urinary tract symptoms (LUTS) are common conditions that affect older men. The prostate is a small gland found inside the pelvis of men between the penis and the bladder. If it becomes enlarged, it can put pressure on the bladder and interfere with urinating. More common symptoms of prostate enlargement include a frequent need to urinate, difficulty starting to urinate and problems in fully emptying the bladder. It is not known why some men's prostate becomes enlarged, but it's thought to be related to hormonal changes as a man gets older. Some studies have shown that chronic inflammation of the prostate can lead to enlargement of the prostate cells and development of BPH. There are some drug treatments available which help to block the inflammation of prostate cells and relieve symptoms of BPH. Also, there is some evidence that combining certain drugs can relieve symptoms of BPH better than standard single drug treatments. One treatment available for BPH is Tadalafil® tablets, which are said to help reduce symptoms of BPH and improve urine flow, but how well it works is still controversial. The aim of this study is to test a new combination drug called Profluss® to see if it works better at relieving the symptoms of BPH and LUTS than Tadalafil®.

Who can participate?
Men aged 50-75 with prostate enlargement.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given Profluss® tablets and take one a day for 6 months. Those in group 2 (control group) are given Tadalafil® tablets and take one a day for 6 months. At the start of the study, all participants complete questionnaires and have urine tests used to assess BPH, then again at 1, 3 and 6 months.

What are the possible benefits and risks of participating?
Participating in this study may help patients reduce symptoms of BPH and LUTS. There is a possible risk of side effects related to the prescribed drugs, however all risks are fully discussed with participants before the start of the trial.

Where is the study run from?
University of Catania, G. Rodolico Hospital (Universitaria Policlinico di Catania - POG Rodolico) and 27 other hospitals in Italy

When is the study starting and how long is it expected to run for?
May 2015 to November 2016

Who is funding the study?
Konpharma SRL (Italy)

Who is the main contact?
1. Prof G Morgia (scientific)
2. Dr GI Russo (public)

Contact information

Type(s)
Scientific

Contact name
Prof Giuseppe Morgia

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Italy
95100

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39/15

Study information

Scientific Title
Serenoa repens, lycopene and selenium vs. phosphodiesterase type 5 inhibitor (PDE5 inhibitor) for the treatment of lower urinary tract symptoms (LUTS)/benign prostatic hyperplasia (BPH): the Sprite study

Study objectives
To evaluate the efficacy and tolerability of the combination therapy Serenoa repens, selenium and lycopene (Profluss®) versus a PDE5 inhibitor (Tadalafil® 5 mg) for 6 months for the treatment of LUTS/BPH.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Polyclinic Hospital, University of Catania, 10/04/2015, ref: 39/2015

Study design
Randomised non-inferiority multicentre study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
1. Group A Serenoa repens 320mg, selenium and lycopene (Profluss ®) 1 tablet per day for 6 months.
2. Group B Tadalafil® 5mg 1 tablet a day for 6 months

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
1. Serenoa repens 320mg, selenium and lycopene (Profluss ®) 2. Tadalafil® 5mg

Primary outcome measure
1. Mean change of international prostate symptom score (IPSS) and peak flow in patients treated with Profluss® or Tadalafil® 5mg. The study is designed as non-inferiority study with a 95% power and an equivalence margin of 0.5 for IPSS and of 0.8 for the peak flow.
2. IPSS quality of life (QoL) questionnaire
3. Maximum urinary flow rate (Qmax uroflowmetry)
4. International Index of Erectile Function (IIEF-5) score

Secondary outcome measures
Mean changes of post-void residual (PVR) volume in patients treated with Profluss® or Tadalafil® 5 mg at enrollment (visit 0), one month (visit 1), at 3 months (visit 2), at 6 months (visit 3)

Overall study start date
01/05/2015

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Age between 50 and 75
2. Digital rectal examination negative for prostate cancer
3. Prostate specific antigen (PSA) <4ng/ml
4. IPSS ≥12
5. PVR <100 ml
6. Peak flow between 4 and 15ml/s

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
600

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. Antiandrogens, 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 5ARI, PDE-5i or surgical treatment for LUTS/BPH.
3. Patients with catheter or with an episode of acute retention of urine in the last 3 months

Date of first enrolment
01/06/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Italy

Study participating centre
University of Catania, G. Rodolico Hospital (Universitaria Policlinico di Catania - POG Rodolico)
Department of Urology (UOC di Urologia)
Catania
Italy
78-95123

Study participating centre
University of Florence (Università degli Studi di Firenze)
Urology Clinic (Clinica Urologica)
Florence
Italy
50121

Study participating centre
University of Rome Tor Vergata (Università Tor Vergata Roma)
Urology Clinic (Clinica Urologica)
Rome
Italy
00173

Study participating centre

University of Perugia (Università degli Studi di Perugia)
Urology Clinic (Clinica Urologica)
Perugia
Italy
06100

Study participating centre
University of Novara (Università degli Studi di Novara)
Urology Clinic (Clinica Urologica)
Novara
Italy
-

Study participating centre
University of Sassari (Università degli Studi di Sassari)
Urology Clinic (Clinica Urologica)
Sassari
Italy
07100

Study participating centre
AO Clinical Institutes of Improvement in Milan (AO Istituti Clinici di Perfezionamento di Milano)
Urology Service (Servizio Urologia)
Milan
Italy
20154

Study participating centre
Buccheri La Ferla Hospital (Ospedale Buccheri La Ferla)
Urology Division (Divisione Urologia)
Palermo
Italy
90123

Study participating centre
Civil Hospital Lucca (Ospedale Civile Lucca)
Urology Division (Divisione Urologia)
Lucca
Italy
-

Study participating centre
Civil Hospital of Avellino (Ospedale civile di Avellino)
Urology division (Divisione Urologia)
Avellino
Italy
83100

Study participating centre
Hospital of Ravenna (Ospedale di Ravenna)
Urology division (Divisione Urologia)
Ravenna
Italy
-

Study participating centre
Hospital Dir UO Div Urologica OC Lugo
Urology Division (Divisione Urologia)
Lugo di Romagna
Italy
-

Study participating centre
Urology of the New Hospital (Urologia del Nuovo Ospedale)
Urology division (Divisione Urologia)
Prato
Italy
-

Study participating centre
Regina Margherita Hospital (Ospedale Nuovo Regina Margherita)
Urology Division (Divisione Urologia)
Rome
Italy
00153

Study participating centre
Hospital SS Annunziata (Ospedale SS Annunziata)
Urology Division (Divisione Urologia)
Cuneo

Savigliano
Italy
12038

Study participating centre
Hospital Santa Croce (Presidio Ospedaliero Santa Croce)
Urology Division (Divisione Urologia)
Fano Pesaro Urbino
Italy
61032

Study participating centre
United Hospitals of Ancona (Ospedali Riuniti di Ancona)
Urology Division (Divisione Urologia)
Ancona
Italy
-

Study participating centre
Urology Hospital Frascati (Urologia Ospedale Frascati)
Urology Division (Divisione Urologia)
Frascati
Italy
-

Study participating centre
Fatebenefratelli Hospital (Ospedale Fatebenefratelli)
Urology Division (Divisione Urologia)
Rome
Italy
00186

Study participating centre
Cardarelli Hospital (Ospedale Cardarelli)
Urology Division (Divisione Urologia)
Napoli
Italy
80131

Study participating centre
Palermo Civic Hospital (Ospedale Civico Palermo)
Urology Division (Divisione Urologia)
Palermo
Italy
90127

Study participating centre
ASP Catania
Urology Division (Divisione Urologia)
Acireale
Italy
-

Study participating centre
Hospital Riuniti (Ospedale Riuniti)
Urology (UOC Urologia)
Reggio Calabria
Italy
-

Study participating centre
Daughters of St. Camillus (Figlie di San Camillo)
Urology Division (Divisione Urologia)
Rome
Italy
-

Study participating centre
ASL di Collegno e Pinerolo Hospital (ASL di Collegno e Pinerolo)
Urology Division (Divisione Urologia)
Torino
Italy
-

Study participating centre
Hospital Garibaldi (Ospedale Garibaldi)
Urology (UOC Urologia)
Catania
Italy
95124

Study participating centre
Civic Hospital (Ospedale Civico)
Urology (UOC Urologia)
Palermo
Italy
90127

Study participating centre
Nursing Home Fabia Mater (Casa di Cura Fabia Mater)
Urology Division (Divisione Urologia)
Rome
Italy
00171

Sponsor information

Organisation
Konpharma SRL

Sponsor details
Via Pietro Della Valle 1
Rome
Italy
00193

Sponsor type
Industry

ROR
https://ror.org/052hty126

Funder(s)

Funder type
Industry

Funder Name
Konpharma SRL (Italy)

Results and Publications

Publication and dissemination plan
The trialists are planning to disseminate preliminary results in the form of an abstract in December 2017, and the full results in June 2018.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Giorgio Ivan Russo upon publication of the paper. Consent was obtained, all data are anonymous.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		06/11/2017	15/11/2017	No	No
Results article	results	01/08/2018		Yes	No