ISRCTN18705154 https://doi.org/10.1186/ISRCTN18705154

The effect of Epilobium angustifolium L. supplement on prostate health

Submission date	Recruitment status	[X] Prospectively registered
08/06/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/06/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/08/2021	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Benign prostate enlargement is where the prostate (a small gland found near a man's bladder) is bigger than usual. The most common complication of BPH that requires hospitalization is acute urinary retention (painful inability to urinate), which greatly affects quality of life and is an important health issue. Many of the other complications of BPH are in part due to complications of chronic (long-term) urinary retention. These complications include recurrent urinary tract infections, formation of bladder stones, hematuria (blood in the urine), and damage to bladder wall and kidneys. The main BPH drug treatments are α-blockers and 5α-reductase inhibitors, such as tamsulosin and finasteride, respectively. Although the adverse effects of these drugs do not occur frequently, they can significantly affect sexual function. Epilobium Angustifolium L. (also known as Epilobium) is a plant that has been used in traditional Chinese medicine for the treatment of traumatic injuries, localized inflammation and disorders related to the menstrual cycle. Considering that prostatic inflammation plays an important role in BPH, the aim of this study is to find out whether a daily intake of Epilobium for a period of at least 5 months improves symptoms and urinary flow in men with mild/moderate BPH.

Who can participate?
Men aged over 45 with mild/moderate BPH

What does the study involve?
Participants are randomly allocated to take one capsule per day containing either Epilobium or placebo for at least 5 months. Clinical visits are carried out after 15 days of treatment to monitor possible kidney and liver toxicity, and after 2 and 5 months of treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improved BPH symptoms. There are no known risks to participants, considering the traditional use of Epilobium for the maintenance of urinary tract health. Nevertheless, in the clinical trial, kidney and liver toxicity tests are carried out, including blood tests.

Where is the study run from?
UCCP (Center for Primary Care), Benevento (Italy)

When is the study starting and how long is it expected to run for?
July 2019 to December 2020

Who is funding the study?
EPO Srl (Italy)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EPIProst0120

Study information

Scientific Title
Double-blind, randomized, parallel-group, monocentric, placebo-blind study of the effect of an extract of Epilobium angustifolium L. with high oenothein B content on benign prostatic hypertrophy (BPH)

Acronym
EPIProst

Study objectives
The clinical study purpose is to evaluate if a daily intake of a food supplement based on E. angustifolium extract with high oenothein B content, for a period of at least 5 months may allow a significant improvement in symptoms in subjects with mild/moderate BPH.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2020, ASL Benevento Ethics Committee (Via Oderisio, n1, 82100, Benevento, Italy; +39 (0)824308419/421; comitatoetico@aslbenevento1.it), ref: 10534

Study design
Interventional double-blind placebo-controlled randomised parallel single-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild/moderate benign prostatic hypertrophy (BPH)

Interventions
The randomization sequence will be generated by a statistician using STATA 16 software (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC), and participants (compliant to the inclusion and exclusion criteria) will be assigned to each of the two treatment groups (Epilobium and placebo) randomly and unpredictably by simple randomization (about 1:1 allocation ratio). The randomization code will consist of a three-digit number as indicated in the respective Case Report Form (CRF).

Treatment: one hard gastro-resistant capsule per day containing 0.5 g of Epilobium, corresponding to 2 g of aerial parts of E. angustifolium, or placebo, for at least 5 months.

Clinical visits are carried out at t1 (after 15 days of treatment) to monitor a possible occurrence of kidney and liver toxicity, t2 (after 2 months of treatment), and t3 (after 5 months of treatment) in an outpatient setting. After each clinical visit, all data are compiled in the CRF by physicians. At the baseline visit (t0) information on the sociodemographic, clinical and symptomatologic characteristics of the subjects are collected and reported in the case report form (CRF). In particular, post-void residual (PVR) and prostate volume (and weight) obtained by prostate ultrasound; PSA, neutrophil/lymphocyte ratio (N/L) derived from blood tests analysed by Unisannio Lab (San Giorgio del Sannio, BN, Italy); urinations number during the night before the clinical visit, and IPSS score are registered.

In detail, the specific analyses are shown below:
t0: Ecovol, PVR (Ecormp), PSA, N/L, CRE, BR direct/indirect/total, Prothrombin, AST, ALT, CHE
t1: CRE, BR direct/indirect/total, Prothrombin, AST, ALT, CHE
t2: PSA, N/R, CRE, BR direct/indirect/total, Prothrombin, AST, ALT, CHE
t3: Ecovol, PVR (Ecormp), PSA, N/R, CRE, BR direct/indirect/total, Prothrombin, AST, ALT, CHE

Abbreviations: Ecovol (prostate volume), post-void residual volume (PVR or Ecormp), prostate-specific antigen (PSA), neutrophil/lymphocyte ratio (N/L), creatinine (CRE), bilirubin (BR direct /indirect/total), prothrombin, aspartate transaminase (AST), alanine transaminase (ALT), cholinesterase (CHE).

Intervention Type
Supplement

Primary outcome(s)
Post-void residual volume (PVR or Ecormp) and prostate volume (and weight), both measured using prostatic ultrasound at baseline (t0) and after 5 months (t3)

Key secondary outcome(s))
Symptomatology assessed at t0, t2, t3 using the following:
1. International Prostatic Symptoms Score (IPSS)
2. Number of urinations during the night before the clinical visit measured by a questionnaire
3. Neutrophil/lymphocyte ratio (N/L) measured by blood analysis
4. Prostate-specific antigen (PSA) measured by blood analysis

Completion date
15/12/2020

Eligibility

Key inclusion criteria
1. Aged over 45
2. No clinically significant deviation in laboratory tests
3. History of mild BPH for at least 1 year
4. Pharmacologically treated but not controlled BPH
5. IPSS score ≥ 8 and ≤ 19 (moderate symptoms)
6. Prostate volume ≥ 25cc and ≤ 70cc
7. PVR between 30 ml and 200 ml
8. PSA ≤ 4 ng/ml

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
128

Key exclusion criteria
1. Acute or chronic disease that could interfere with the study or dangerous for the participant
2. Use of any of the following concomitant drugs: immunosuppressants, anticoagulants, α-blockers, 5α-reductase inhibitors, antipsychotics, chemotherapy drugs, drugs for dementia, male hormone replacement therapy and drugs for overactive bladder, atonic and/or neurogenic bladder
3. Bladder neck contracture
4. Acute prostatitis; bladder calculosis: urinary tract infection more than once in the last 12 months
5. Prostate or bladder cancer; history of pelvic trauma or surgery; clinically significant kidney or hepatic insufficiency
6. Microscopic hematuria that was not evaluated by a urologist and not attributed to BPH
7. Any condition that might interfere with the subject's ability to give informed consent, to comply with study instructions, to provide an objective evaluation of his or her symptoms, or that might confuse the interpretation of study results
8. Those considered unsuitable for the participation by the physician

Date of first enrolment
22/06/2020

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Italy

Study participating centre
UCCP (center for primary care)
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Italy
82100

Sponsor information

Organisation
EPO Srl

Funder(s)

Funder type
Industry

Funder Name
EPO Srl

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 Dr Giuseppe Buonomo (giuseppebuonomo@tin.it).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	13/08/2021	Yes	No
Participant information sheet			03/07/2020	No	Yes
Protocol file			03/07/2020	No	No