

The effect of *Epilobium angustifolium* L. supplement on prostate health

Submission date 08/06/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/08/2021	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

Plain English Summary

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 5 α -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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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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 oenothelin B content on benign prostatic hypertrophy (BPH)

Acronym

EPIProst

Study hypothesis

The clinical study purpose is to evaluate if a daily intake of a food supplement based on *E. angustifolium* extract with high oenothelin 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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See additional files

Condition

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 (Ecomp), 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 (Ecomp), PSA, N/R, CRE, BR direct/indirect/total, Prothrombin, AST, ALT, CHE

Abbreviations: Ecovol (prostate volume), post-void residual volume (PVR or Ecomp), 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 measure

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

Secondary outcome measures

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

Overall study start date

20/07/2019

Overall study end date

15/12/2020

Eligibility

Participant 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 $\geq 25\text{cc}$ and $\leq 70\text{cc}$
7. PVR between 30 ml and 200 ml
8. PSA ≤ 4 ng/ml

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

128

Total final enrolment

128

Participant 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, 5 α -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

Recruitment start date

22/06/2020

Recruitment end date

30/06/2020

Locations

Countries of recruitment

Italy

Study participating centre

UCCP (center for primary care)

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Sponsor information

Organisation

EPO Srl

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Sponsor type

Industry

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Funder(s)

Funder type

Industry

Funder Name

EPO Srl

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-review journal

Intention to publish date

01/06/2021

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?
Participant information sheet			03/07/2020	No	Yes
Protocol file			03/07/2020	No	No
Results article		01/06/2021	13/08/2021	Yes	No