A CLINICAL STUDY TO EVALUATE EFFECT OF PRUNUS DOMESTICA (PROSMAN™) ON BENIGN PROSTATE HYPERPLASIA (BPH)

Dr S.N. Sankhwar1, Dr NarSingh Verma1, Apurva Goel1, Kiran Tiwari1
1. Professor and Head, Department of Urology, King George’s Medical University, Lucknow, U.P, India. 2. Professor, Department of Physiology, King George’s Medical University, Lucknow, U.P, India.

ABSTRACT
Benign prostate hyperplasia (BPH), a non-malignant enlargement of prostate, is majorly witnessed in men over the age of 60. The active constituents of Prunus Domestica extract (Prosm) include phytosterols that have anti-inflammatory effects. In this prostate, Prunus also contains pentacyclic triterpenes that have anti-edema properties, and ferulic acid esters that reduce prolactin levels and block the accumulation of cholesterol in the prostate. The current study aims to evaluate the safety and efficacy of Prunus Domestica extract (Prosm) in humans suffering from Benign Prostate Hyperplasia (BPH). This open labeled and single armed study, conducted at King George’s Medical University (KGMU), Lucknow was carried out on Indian population suffering from BPH. A total of 140 males between 40-65 years were included in the study. Prosm 100 mg was administered to them twice a day for 12 weeks and the effect was investigated using laboratory investigations after 4, 8 and 12 weeks. A reduction in the IPSS score, prostate volume and serum PSA levels was observed. Symptomatic relief was observed in all 140 subjects that took part in the study. Hence, it may be concluded that Prunus Domestica extract (Prosm) can be labeled safe and effective for human consumption.

MATERIALS & METHODS
This was an open labeled and single armed study. The study was carried out on Indian population suffering from BPH. The study was conducted at King George’s Medical University (KGMU), Lucknow.

Study population comprised of males in between age group 40-65 years. A total of 140 subjects were included in the study. The investigation product Prunus Domestica extract (Prosm) 100mg was given twice a day for 12 weeks and was allotted after screening and enrolment of the study subject. The subjects were followed up after 4 weeks, 8 weeks and 12 weeks.

Safety was assessed at each follow-up visit. The efficacy of investigational product Prunus Domestica extract (Prosm) in BPH subjects was evaluated by the laboratory investigations, which included PSA blood test, Utrasound and Urinary flow test.

A prior ethical clearance was taken from institutional Ethical Committee of KGMU. Statistical analysis was done by SPSS 17.0. T test was applied and a p-value of < 0.05 was considered as significant.

INCLUSION CRITERIA
1. Age between 40 and 65 years
2. Only male patients were included
3. Patients suffering from symptoms of BPH for at least 6 months before screening.
4. Patients having prostate volume ≥ 20 mL and ≤ 70 mL as assessed by ultrasonound.
5. Patients having PSA ≥ 8 at screening and baseline.
6. Patients willing to give informed consent in writing.

EXCLUSION CRITERIA
1. Patients suffering from BPH, prostate cancer, or prostatic carcinoma.
2. Patients having bladder neck contracture or urethral stricture.
3. Patients having symptoms of bladder outlet obstruction.
4. Patients having history of prostate surgery or pelvic irradiation.
5. Patients participating in another clinical study.
6. Patients having other urological or systemic diseases.
7. Patients having history of alcohol or drug abuse.
8. Patients having a history of allergic reaction to the Investigational Product.
10. Patients who are pregnant or breastfeeding.

RESULTS
The study was conducted on 140 male study subjects in between age group 40-65 years. Average age of the study population was 56.08 years, with minimum age as 40 years and maximum age as 65 years. Prunus Domestica extract (Prosm) was effective in BPH patients as reduction in the IPSS score, prostate volume and serum PSA levels were observed. Symptomatic relief was observed in all 140 subjects that took part in the study.

EFFICACY CONCLUSIONS

a) IPPS Score
A highly significant decrease (p<0.001) in IPPS score was observed after 4 weeks, 8 weeks and on completion of the treatment as compared to baseline value. Product showed efficacy within first four weeks of the treatment. All enrolled patients reported decrease in IPPS score on completion of the treatment.

b) Effect on Prostate Volume
Highly significant decrease in the prostate volume was observed after 4 weeks, 8 weeks and on completion of the treatment. The decrease in prostate volume was 29.46%. 94% of the patients showed decrease in prostate volume.

c) Effect on Serum Prostate Specific Antigen Levels (PSA)
A significant decrease in the serum PSA levels was observed. The decrease in serum PSA levels was 56%. 76% of the patients showed decrease in the serum PSA levels on completion of treatment.

SAFETY EVALUATION
No significant change in the liver function tests (serum SGOT, SGPT & ALP activities) was observed. No significant change in the serum urea levels and creatinine level were observed. Further, no significant change in the hematological parameters was observed on completion of the treatment.

DECLARATION OF CONFLICT OF INTEREST - Observation was sponsored by Chemical Resources 3 R & D, Chemical Resources, Pancharia, Haryana, India.

BACKGROUND
Benign prostate hyperplasia (BPH) is a non-malignant enlargement of the prostate. Majority of men over the age of 60 are considered to have urinary symptoms attributable to BPH. The active constituents of Prunus Domestica extract (Prosm) include phytosterols (e.g. beta-sitosterol) that have anti-inflammatory effects by inhibiting production of pro-inflammatory prostaglandins in the prostate. Prunus also contains pentacyclic triterpenes (ursolic and oleanic acids) that have anti-edema properties, and ferulic acid esters (n-docosanol and tetracosanol) that reduce prolactin levels and block the accumulation of cholesterol in the prostate.

AIM OF THE STUDY
The aim of the study was to evaluate the safety and efficacy of Prunus Domestica extract (Prosm) in humans suffering from Benign Prostate Hyperplasia (BPH).

EXCLUSION CRITERIA
1. Patients having neurogenic bladder dysfunction.
2. Patients having bladder neck contracture or urethral stricture.
3. Patients having acute or chronic prostatitis or urinary tract infection.
4. Patients having history of prostate cancer or carcinoma of the prostate suspected on digital rectal exam.
5. Patients participated in any other clinical trial within last 30 days.
6. Patients having resting systolic blood pressure (BP) > 160 mmHg or < 90 mmHg, or diastolic BP > 90 mmHg or < 60 mmHg at screening.
7. Patients having urine loss < 5 ml/sec.
8. Patients using other herbal medications for treatment of BPH, associated symptoms and Erectile Dysfunction in past 1 month.
10. Patients gone through radiotherapy previously.

RESULTS
- Efficacy and safety data in the current clinical study in BPH patients clearly shows that the Investigational Product (Prunus Domestica extract) is effective and safe.
- Prunus Domestica Extract is able to safely reduce the IPPS score, Prostate volume, and PSA levels drastically on completion of the treatment in BPH patients.
- Prunus Domestica extract is also proved to be completely safe in BPH patients.