Product Profile: Procianidol

Manufacturer	**Bruschettini s.r.l., Italy**
U.S. distributor	None
Botanical ingredient	**Grape seed fermented product**
Extract name	N/A
Quantity	100 mg
Processing	No information
Standardization	No information
Formulation	Capsule

Source(s) of information: Fusi et al., 1990.

Clinical Study: Procianidol

Extract name	N/A
Manufacturer	Bruschettini s.r.l., Italy
Indication	**Vision**
Level of evidence	**II**
Therapeutic benefit	**Trend**

Bibliographic reference
Fusi L, Czimeg F, Pesce F, Germogli R, Boero A, Vanzetti M, and Gandiglio G (1990). Effects of procyanidolic olygomers from *Vitis vinifera* in subjects working at video-display units. *Annali di Ottalmologia e Clinica Oculistica* 116: 575-584.

Trial design
Parallel. Three-arm treatment: Group 1 included 50 subjects treated with procyanidolic oligomers; group 2 included ten subjects treated with bilberry anthocyanosides at a dose of 1 × 100 mg capsule three times daily; and group 3 included 15 subjects treated with placebo.

Study duration	2 months
Dose	1 (100 mg) capsule 3 times daily procyanidolic oligomers
Route of administration	Oral
Randomized	Yes
Randomization adequate	No

Study duration	4 months
Dose	1 to 2 tablets 3 times daily
Route of administration	Oral
Randomized	No
Randomization adequate	No
Blinding	Open
Blinding adequate	No
Placebo	No
Drug comparison	Yes
Drug name	Tadenan
Site description	Not described
No. of subjects enrolled	89
No. of subjects completed	89
Sex	Male
Age	50-68 years

Inclusion criteria
Patients with clinical stages I and II benign prostate hyperplasia, with a short history of symptoms no longer than a few weeks in duration (classification system not given).

Exclusion criteria
Patients with complete urine retention.

End points
Subjective assessment was made using a symptom score system and objective evaluation by physical examination, uroflowmetry, and ultrasound examination of residual urine and prostate size.

Results
The therapeutic response was positive in 40 (78 percent) and 21 (55 percent) patients in the Cernilton and Tadenan groups, respectively. Peak flow rate improved by 19.5 percent in the Cernilton group, and by 10.8 percent in the Tadenan group. Residual urine volume improved by 47.8 percent and by 21.6 percent in the Cernilton and Tadenan groups, respectively. Prostate volume also improved by 5.15 percent (Cernilton) and by 0.45 percent (Tadenan). Obstructive symptom scores improved by 62.75 percent in the Cernilton group and by 45.8 percent in the Tadenan group. Irritative symptoms improved in the Cernilton group by 68.4 percent and by 40 percent in the Tadenan group.

Side effects
No adverse reactions were seen.

Reviewer's comments
Although this study gave negative results, the sample size was small, and the subjects were not randomized or blinded. (1, 5)

Clinical Study: Lipton® Research Blend

Extract name	None given
Manufacturer	Thomas J. Lipton Co.
Indication	**Antioxidant activity** in healthy volunteers
Level of evidence	**III**
Therapeutic benefit	**MOA**

Bibliographic reference
Leenen R, Roodenburg AJC, Tijburg LBM, Wiseman SA (2000). A single dose of tea with or without milk increases plasma antioxidant activity in humans. *European Journal of Clinical Nutrition* 54 (1): 87-92.

Trial design
Crossover. Each subject received six treatments on six different days with at least two days in between. After an overnight fast, volunteers were given a single dose of black tea, green tea, or water, with or without milk.

Study duration	1 day
Dose	2 g tea solids in 300 ml water (equivalent to 3 cups of tea)
Route of administration	Oral
Randomized	Yes
Randomization adequate	No
Blinding	Open
Blinding adequate	No
Placebo	Yes
Drug comparison	Yes
Drug name	Black tea
Site description	Single center
No. of subjects enrolled	24
No. of subjects completed	21
Sex	Male and female
Age	18-65 years

and to placebo. Subjective heart failure symptoms were significantly reduced by both doses compared to placebo (Tauchert, 2002).

Faros 300

Chronic Heart Failure

Four trials were reviewed that evaluate the use of Litchwer's extract LI 132 for patients with NYHA Class II heart failure. The trials used a dose ranging from 100 to 300 mg three times daily for a period of one to two months. The largest trial, which was rated as being of good quality, included 124 subjects, and compared the effectiveness of LI 132 (300 mg three times daily) with captopril (12.5 mg three times daily). Captopril is an ACE (angiotension converting enzyme) inhibitor that lowers blood pressure in hypertensive individuals and reduces peripheral resistance of blood vessels. In this trial, both LI 132 and captropril equally improved exercise capacity and decreased a measured product of heart rate and blood pressure after two months of treatment (Tauchert, Ploch, and Hübner, 1994).

Three smaller trials, with about 70 subjects each, were placebo-controlled. One of them, using a dose of 200 mg three times daily for two months, reported a statistical improvement in exercise capacity and a decrease in the measured product of heart rate and blood pressure compared to placebo (Schmidt et al., 1994). Another trial, using a dose of 300 mg three times daily, showed only a trend toward an increase in exercise capacity, but reported a significant increase both in exercise time taken to reach anaerobic metabolism and in oxygen absorbed by the lungs both during exercise and afterward (Forster et al., 1994). The final study used a smaller dose (100 mg three times daily) for short period of time (only one month) and showed statistically insignificant increases in exercise capacity compared with placebo (Bodigheimer and Chase, 1994).

POSTMARKETING SURVEILLANCE STUDIES

A study including 940 medical practioners and 3,664 patients diagnosed with cardiac insufficiency NYHA Class I or Class II documented a therapeutic benefit in 1,476 patients given hawthorn and no