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Study summary

Efficacy and safety of Purslane Herb Extract in type II diabetic patients: A double-blind, placebo controlled clinical study

Objective

Maintaining a healthy blood sugar range has a significant impact on an individual's health, quality of life as well as life expectancy. In Near Eastern folk medicine purslane herb is traditionally used for its antidiabetic properties. Preclinical studies in rats confirmed the plant's beneficial effects on blood glucose metabolism. Guided by bioactivity testing, Frutarom has developed Portusana®, a highly concentrated source of purslane, acting on three key mechanisms of glucose metabolism.
Preliminary data showed the blood glucose lowering effect of Frutarom's purslane herb extract in humans. In order to prove the efficacy, safety and tolerability of the extract for long term glucose control, a clinical study was conducted in type 2 diabetic patients.

Study design

The study, a randomized, double blind, parallel group, placebo-controlled trial, was conducted at the E.Wolfson Medical Center, Holon (Israel). It was approved by the Ethics Committee.
The participants consisted of a total of 63 males and females, type 2 diabetic patients aged between 35-75, with glycosylated hemoglobin HbA1c 6.2 – 11 % and BMI 25-35. Excluded were patients on insulin therapy or treated with more than one hypoglycemic drug.
The participants were randomized to treatment with either purslane herb extract (PE), equivalent to 3 x 60 mg/day Portusana®, or matching placebo, provided in capsules. After a 2-week placebo run-in, treatment was taken during 12 weeks.

Assessments included weight, height, blood pressure, heart rate, hematology and measures of glucose homeostasis, including HbA1c. Safety assessment measures included monitoring of adverse events, standard hematology and urinalysis. HbA1c is a long term marker for blood glucose control, strongly associated with an increased risk for developing cardiovascular disorders. HbA1c levels depend on the blood glucose concentration and reflect the average glucose levels over the prior two to three months.

Results

At baseline, the two treatment groups were comparable with respect to demographic data and medical condition. Measures of glucose homeostasis, including HbA1c, fasting insulin, HOMA-IR body weight, and BMI, all declined from baseline in both groups. However, significant differences between groups were not detected. Systolic blood pressure declined in both treatment groups but the decline was significantly greater in the PE group.
Noticeably, in the group of participants defined as responders (participants whose HbA1c level at end of study was lower than the baseline level, regardless of treatment assignment), while HbA1c declined in both groups, after 12 weeks of treatment, Frutarom's purslane herb extract significantly reduced the level of HbA1c compared to placebo. The reduction amounted to -0.81 ± 0.4 versus -0.59 ± 0.5, respectively, and outperformed placebo by 44%. (Fig. 1). No other changes in glucose control parameters were noted.

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A subgroup analysis in responders according to the oral hypoglycemic medicine received before the study, revealed that responders subjects treated with biguanides the change from baseline of HbA1c was significantly greater in the Purslane extract group.
No serious adverse events were recorded and the extract was well tolerated throughout the study period.

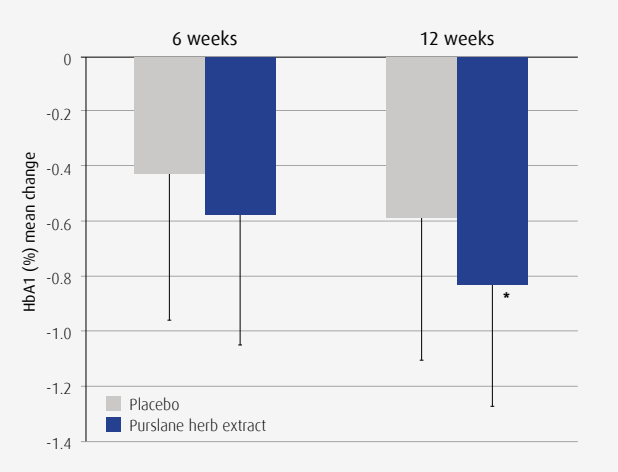

Fig. 1: Significant improvement of HbA1c with purslane herb extract in responding patients. Data represent the difference from baseline of HbA1c * $p<0.05$

Summary

The findings of this clinical study showed that Frutarom's purslane herb extract is efficient in improving blood glucose control in type 2 diabetic patients as demonstrated by the reduction in HbA1c after 12 weeks of treatment. Average HbA1c could be reduced by 0.81% points. HbA1c reduction is one key approach which can significantly improve long term health.
Additionally, the extract did not alter insulin levels. Therefore, it can be assumed that hypoglycemic states, a well-known adverse effect of oral antidiabetic drugs stimulating insulin secretion, are not to be expected.

These results amend the findings of the open application trial confirming that Frutarom's purslane herb extract not only decreases blood glucose levels but also specifically lowers the long term blood glucose marker HbA1c.
Based on the above, it may be concluded that Frutarom's purslane herb extract efficiently assists blood glucose regulation, is well tolerated and may help protect the body from the negative effects resulting from high blood sugar levels.

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