Efficacy of a dietary supplement designed to stimulate chemosensory receptors in the gut to reduce hunger: A randomized, double-blind, placebo controlled 7-day field study

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ABSTRACT

BACKGROUND AND PURPOSE:
In previous acute clinical studies, a tablet specially formulated with low calorie, Generally Recognized As Safe (GRAS) dietary ingredients to activate chemosensory receptors on L-cells in the lower gut has been shown to augment the release of satiety hormones PYY and GLP-1.

AIM
To determine whether this proprietary blend of steviol glycosides, polyphenols, punicalagins, and free amino acids could help reduce feelings of hunger and be useful as an aid for weight loss.

SUBJECTS AND METHODS:
This study randomized 220 subjects from 23 states. Study visits were conducted by study pharmacists via scripted telephone calls and electronic mail. Participants were instructed that the primary objective of the study was to assess, over a 7-day period, whether the test product was effective in reducing hunger compared to their usual hunger level prior to the start of the study. Subjects were also asked to report their body weight before starting the study and again at the end of the 7-day study period.

RESULTS:
The active formulation was significantly more effective in reducing hunger than placebo (p-value=0.02, Fisher's Exact Test, 2-tailed analysis).

Fifty-eight percent (N = 57) of the subjects on the active formulation experienced reduced hunger. Eighty-nine percent of this group felt that it was a useful aid for losing weight, and 94% would recommend it to their friends and family. On average, this group lost 1.95 lbs. (1.08% of their body weight) during the 7-day study. Mild adverse events collected during the study were fairly evenly distributed between the active and placebo groups; no safety flags were noted.

CONCLUSIONS:
This specially formulated proprietary blend of GRAS ingredients was effective in reducing hunger and was reported as a useful aid for losing weight. Subjects who experienced reduced hunger on the active formulation lost an average of 1.95 lbs. during the 7-day study period and agreed with at least one of the following statements. Many reported multiple effects; each of the following effects was experienced by approximately 80% of these subjects:

- Felt satisfied/full faster when eating a meal
- Felt satisfied with fewer calories than usual
- Went longer between meals without feeling hungry
- Helped control snacking/eating between meals
- Helped control urge to overeat

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METHODS

Two hundred and twenty subjects were randomized to active formulation or placebo. Tablet bottles were coded by color and label font. Study pharmacists and the subjects were blinded to the formulations represented by the bottle codes. The randomization code was known to only one person employed by the Sponsor and that individual had no direct contact with any of the subjects in the study.

Study conduct included a web based questionnaire and study visits which were conducted by study pharmacists via scripted telephone calls and/or electronic mail. Participants were asked to collect their body weight before the start of and after 1 week of tablet testing. These measurements were reported to a study pharmacist via a telephone call before and after the one week of product testing. Participant's responses pertaining to experience with the tablets used during the week were captured during the telephone visit and entered into the electronic study database. Subjects assigned to twice daily (BID) regimen were instructed to take their assigned tablet(s) 1 to 2 hours before their 2 main meals of the day. Subjects randomized to three times daily (TID) were instructed to take their assigned tablets 30-60 minutes before their usual breakfast, lunch and dinner times. Subjects were told to take their tablets regularly each day during their treatment period even if they planned on skipping a meal.

DEMOGRAPHICS

Of the 220 subjects randomized and sent test materials, 194 (88%) completed the study. The study completers were predominantly female (83.5%) and white (73%); their average weight and age were approximately 192 lbs. and 45 yrs., respectively, at the beginning of the study.

Group	Formulation; Dose	Completers		
		N, (%)	Average Weight ± SD (lbs.)	Percent Female
1	**Active; 1 tab BID**	31, (77.5)	192.1 ± 42.5	93.5
2	**PBO; 2 tabs BID**	29, (67.9)	190.2 ± 43.3	89.7
3	**PBO; 1 tab BID**	28, (93.3)	198.0 ± 42.3	71.4
4	**Active; 2 tabs BID**	33, (89.2)	186.4 ± 39.6	75.8
5	**PBO; 1 tab TID**	38, (95.0)	190.3 ± 41.8	86.8
6	**Active; 1 tab TID**	35, (87.5)	197.0 ± 46.6	82.9
ALL		**194 (88.2)**	**192.3 ± 42.3**	**83.5**

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RESULTS

EFFECT ON HUNGER

"While taking the test product during this past week was your hunger less than your typical level of hunger before the study?"

Hunger less?	Active (n)				Placebo (n)			
	All	1 BID	1 TID	2 BID	All	1 BID	1 TID	2 BID
Yes	57	19	20	18	39	10	13	16
No	42	12	15	15	56	18	25	13
	Active (%)				Placebo (%)			
Yes	58	61	57	55	41	36	34	55
No	42	39	43	45	59	64	66	45

Yes for 'Hunger less?'	All Arms 1BID+1TID+2BID	1 tablet/dose 1BID+1TID	1 BID	1 TID	2 BID
Difference from Placebo (%)	17	24	26	23	-1
p-value*	0.023	0.009	0.062	0.069	1

* Fisher's exact test (2-tailed)

RESULTS

USEFUL PRODUCT?

	Percent Yes			
	1 tab BID	1 tab TID	2 tabs BID	All
Is This Product a Helpful Aid for Losing Weight?	95	88	83	89
Would You Recommend This Product to Friends and Family?	100	88	94	94

Population: Subjects randomized to active who felt reduced hunger and who answered these questions (n=54)

BODY WEIGHT

	Responders (N=56)
Average Starting Weight (lbs)	188.8
Average Weight Change (lbs)	-1.95
Average Weight Change (%)	-1.08

Population: Subjects randomized to active who felt reduced hunger and who reported their weights before and after their 7-day trial period

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EXPERIENCE

Which phrase or phrases best describes how YOU experienced this product working for you? (Choose all that apply)

Description of Experience	Percent of Responders who Agreed
Felt satisfied/full faster when eating a meal	78
Felt satisfied with fewer calories than usual	80
Went longer between meals without feeling hungry	80
Helped control snacking/eating between meals	78
Helped control urge to overeat	81

Population: All subjects randomized to Active who felt reduced hunger and who answered this question (n=54)

Fifty-four of the responders (100%) who answered the question agreed to at least 1 of the statements above. Forty-one percent of those who answered the question agreed with all 5 statements; 30% agreed with 4 of the 5 statements; 17% agreed with 3 statements; 11% agreed to 2 statements and 2% agreed to only 1 of the 5 statements. There were 3 subjects who experienced reduced hunger on the active formulation but did not answer the question.

CONCLUSIONS

This specially formulated proprietary blend of GRAS ingredients was effective in reducing hunger and was reported as a useful aid for losing weight. Subjects who experienced reduced hunger on the active formulation lost an average of 1.95 lbs. during the 7-day study period and agreed with at least one of the following statements. Many reported multiple effects; each of the following effects was experienced by approximately 80% of these subjects:

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