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aXivite, a safe and effective treatment for healthy weight loss and improved body shape while simultaneously mitigating the effects of GI inflammation

Safety, bioefficacy and health benefits of aXivite

Key Words: aXivite, weight loss, body fat, gut health, zonulin

Summary

aXivite (phenylcapsaicin) is a novel functional ingredient derived from the natural compound, capsaicin.

In a recently completed healthy human, blinded, randomized, clinical study, aXivite demonstrated statistically significant body fat loss, an improved body-shape and lean mass profile and improved gut health, as measured by an decrease in serum zonulin.

At both the low and high dose tested, aXivite showed excellent tolerability and safety profile over the 8 week treatment period.

The study titled, "Effects of Phenyl-Capsaicin on Weight Loss and Body Composition" was conducted at the Center for Applied Health Sciences. The eight-week study was conducted as a randomized, double-blind, parallel-group clinical trial of male and female subjects recruited at a single investigational center in Northeast Ohio. The study was conducted following ICH-GCP guidelines to ensure subject safety and scientific integrity of the data.

39 patients completed the study - 12 placebo treated, 15 high dose (1,12 mg/day) aXivite treated and 12 low dose (0,560 mg/day) aXivite treated.

Safety

Capsaicin has been used as a traditional medicine for over a thousand years. It has a long list of successful safety studies that show it is safe for both animal and human consumption. Recent safety studies on aXivite have indicated the same excellent safety profile. (*Paulsen et al.*)

This clinical study lends further support to this excellent safety profile. Over the 8 week period, no SAE or AE's were reported at both doses. Serum creatinine, lipid profile and blood pressure showed no change over the 8 week treatment period at low and high dose aXivite. No serious AE's were observed with either low or high dose groups. Also, no clinically relevant changes were observed in objective biomarkers of health (e.g., vital signs, clinical blood chemstries, hematology). Any non-serious AE's were generally mild in intensity and resolved completely by the end-of-study.

Reduction in Body Fat and achieving a healthier Body Shape

The low dose of aXivite showed a significant decrease of 5.44% in the DXA total body fat measurement ($p=0.001$), when using the high dose of aXivite as a non-responsive base-line.

The low dose treatment also showed a statistically significant but more moderate reduction of 2.39% versus the negative trending placebo ($p=0.06$).

The total body fat reduction was further corroborated for the low dose aXivite treatment, with the DXA percent body fat measurement which showed a 3.48% reduction versus the non-responsive high dose ($p=0.001$) and a 1.85% reduction versus the placebo group ($p=0.04$).

As an indication that increased fat burn is the likely physiological mechanism of action, the low dose aXivite treatment also showed a significant improvement in visceral adipose tissue, with a reduction of 14.7% versus the positive-responding high dose ($p=0.06$) but not a significant reduction (2.28%) versus the placebo group.

As one would expect, this fat reduction also led to a healthier body shape and lean:fat ratio.

The healthier body shape was quantified by a statistically significant decrease in hip circumference of 2.1 cm for the low dose treatment group ($p=0.003$).

The improved lean:fat ratio ($p=0.002$) with the low dose treatment was further boosted by a small but not statistically significant increase in lean mass. A greater number of subjects would have likely made this result statistically relevant.

Zonulin and Gut Health

Serum levels of the critical gut barrier marker, zonulin, showed a statistically significant decrease of 9.2 ng/mL ($p=0.088$) for the low dose treatment group over the 8 week period. Human zonulin is a protein that increases permeability in the epithelial layer of the small intestine by reversibly modulating the intercellular tight junctions. Serum zonulin levels have been shown to be significantly higher in patients with Crohn's disease, IBD and smokers (*Malickova et al.*) and treatment that lowers this circulatory marker can be considered a method to promote improved gut health.

Appetite

In a self-administered questionnaire, subjects indicated a noticeable decrease in appetite and sweet-cravings. These results did not get corroborated with a change in serum ghrelin levels (ghrelin is a hunger signal, released by the stomach), but they were reflected in a modest, consistent increase in serum adiponectin level.

Adiponectin plays an important role in the regulation of glucose and lipid metabolism and possesses insulin-sensitizing and anti-inflammatory properties which may influence GI and CNS disorders.

Conclusions

1. aXivite (phenylcapsaicin) is a well-studied synthetic capsaicin which is being developed for multiple nutraceutical and pharmaceutical applications.
2. aXivite's gut-health mechanism of action is particularly associated with reduced inflammation, occurring via a statistically significant reduction in serum zonulin levels.
3. This clinical study has demonstrated a metabolic role for aXivite that induces increased fat-burn leading to healthy weight loss and body shape in healthy subjects.
4. Unpublished and published data with aXivite treatment, including this clinical study, continue to demonstrate an excellent safety and tolerability profile at both high (1,12 mg/day) and low (0,560mg/day) doses.

References

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