

Undenatured Beta-Glucan and Improvement in Quality of Life in Humans

Bjørn Kristiansen¹, Ronald J. Amen^{2*}

¹Department of Clinical Research, Glycanova AS, Fredrikstad, Norway; ²Department of Clinical Research, Tech Enterprise LLC, California, USA

ABSTRACT

Beta-glucans from various sources have been reported to have some positive effects on the immune system in animals and humans. Our earlier research showed that undenatured beta-glucans from mushrooms, found in nature as β -1,3 beta-glucan with β -1,6 branching and a molecular weight typically of $\geq 500,000$ Da, increased specific cytokines and chemokines when compared to denatured beta-glucans.

Key words: Immune system; Beta-glucan; Quality-of-Life; Safety concerns; Clinical studies

ABOUT THE STUDY

Safety in animal models was demonstrated, and human safety studies in different “fatigue” models were initiated [1]. As part of the safety evaluation the subjects were asked to respond to a series of questions that reflected their daily condition (i.e. Quality-of-Life) periodically during the study.

In the first controlled study 44 subjects who were self-perceived to be fatigued were administered the undenatured beta-glucan to determine if this supplementation affected their Quality-of-Life as a result of an increased immune system response. 44 subjects were administered 1 mg/mL bid of the undenatured beta-glucan for four weeks [2]. The placebo for all studies was a cellulose solution. Prior to the beginning of the administration, and following the four-week administration period, the subjects were asked to fill out a Quality-of-Life VAS questionnaire. The changes in the two questionnaires revealed differences that occurred as a result of the undenatured beta-glucan administration. More than 75% of the subjects scored “better” (more than 1 cm on the VAS) with regard to feeling in a good mood, and feeling rested. More than 60% increased their energy and reduced their tiredness and exhaustion and 70% felt less stressed. This study showed the change in score from baseline that the subjects on undenatured beta-glucan experienced an improvement in Quality-of-Life (estimate=2.1) [3], whereas the subjects in the placebo group experienced a worsening of life quality (estimate=-6.6) during the study period. The difference between the treatment groups was statistically significant

($p=0.059$). No adverse events or safety concerns were reported for this population.

In a second study, subjects aged 40 years and older, believed to be in good general health, seeking therapy for tiredness/exhaustion/fatigue were administered the same 1 mg undenatured beta-glucan/mL bid. As in the first study, overall results indicated that the subjects felt significantly better (mean VAS=5.91) after the last week of the study compared to how they felt initially (VAS=4.73) ($p<0.0001$) [4]. A statistically significant ($p<0.0001$) change in distribution favouring a better situation after four weeks of ingestion of the supplement, with a remarkable fall in number of subjects scoring below normal (from 61.4% to 18.2%) accompanied by a significant shift in subjects feeling above normal, from 9.2% to 50.0%. The subjects had statistically significant improvements in overall Quality-of-Life as reflected in a reduction of depression, fatigue, and stress, and improvements in mood, energy, happiness, and initiative. More than 60% stated that they had increased energy and reduction in tiredness and exhaustion; and 70% felt less stressed [5]. These clinical studies showed that undenatured beta-glucan administration improved the perceived Quality-of-Life of subjects whose immune system was probably not functioning at optimal levels. No adverse events or safety concerns were reported for this population [6].

Additionally, 30 subjects in a free-living environment, who initially rated themselves under a VAS=6 (normal or average) in half of the eight well-being questions and consumed the

Correspondence to: Ronald J. Amen, Tech Enterprise LLC, California, USA, Tel: +1-818-207-6063; E-mail: ronald.amen@techenterprises.org

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undenatured beta-glucan, reported an average improvement of 1.0 per question [7], relative to the placebo group ($p=0.0007$).

Questionnaires

How did you feel last week?

Have you felt depressed last week?

Did you feel rested and in a good mood when you woke up?

Did you feel active and full of energy last week?

Were you feel happy and care free last week?

Did you feel tired and exhausted last week?

Did you feel relaxed and high spirited or stressed and tense?

Have you felt listless and without initiative last week?

CONCLUSION

Overall, the undenatured beta-glucan group showed an improvement of 0.9 per question across all eight questions relative to placebo ($p=0.0004$). Forty-five of the initial scores in the undenatured beta-glucan treatment group were below three (out of 10) and their average improvement was a highly significant 2.8 ($p<0.0000$). Eighty-seven of the initial undenatured beta-glucan group who had scores that were below four, improved by 2.1 ($p<0.0000$) on average. Additionally, they stated that their overall Quality-of-Life improved over the study period. They indicated that this improvement was manifested by a significant increased energy/decreased fatigue, decreased stress, and decreased depression. The results from this study showed that daily supplementation with the undenatured beta-glucan generated a statistically significant ($p=0.004$) increase in well-being as compared to placebo.

Importantly, the greater the need for improved well-being, indicated by participants reporting lower starting scores on their initial questionnaire, the greater the improvement with undenatured beta-glucan relative to placebo; “the more help needed, the more Lentinex helped”. Again, no adverse events or safety concerns were reported for this population.

REFERENCES

1. Kristiansen B. Immune modulating compounds from fungi. 2010;
2. Kristiansen B, Waddell D. Production of fungal extracellular immune stimulating compounds. 2005.
3. Kristiansen B, Amen RJ. Safety and Efficacy of a Proprietary Undenatured Beta-Glucan on Different Human Populations. *Advances in Biological Chemistry*. 2022; 12: 16-28.
4. Gjertsen B. Evaluation of Lentinex® Toxicity in Healthy BN Rats. Institute of Medicine, Haematology Section, University of Bergen and Department of Internal Medicine, Haematology Section, Haukeland University Hospital, Bergen, Norway. 2006;
5. Fjeldstad B. Effect of Lentinex® in a “Fatigue” Population Visiting an Aroma Therapeutic Clinic: An Opinion Survey. 2008;
6. Fjord ES. Clinical Study Short Report on QoL Dose Escalation Safety Study of Lentinex® in Healthy Subjects: A Double Blind Placebo-Controlled Study, Bergen II, Centre for Clinical Trials (CENCLIN), Gamlehaugvei 20, N-5231 Paradis, Norway. 2008;
7. Gaullier J-M, Sleboda J, Ofjord ES, Ulvestad E, Nurminiemi M, Moe C, et al. Supplementation with a soluble β -glucan exported from Shiitake medicinal mushroom, *Lentinus edodes* (Berk.) singer mycelium: A crossover, placebo-controlled study in healthy elderly. *Int J Med Mushrooms*. 2011; 13: 319-326.