



STUDY SUMMARY

The immunostimulating effect of the Echinacea dry pressed juice EFLA®894 in healthy volunteers

Objective

Preparations from Echinacea purpurea are well documented for their immunostimulant properties and mainly used for the prevention and treatment of upper respiratory tract infections (URTIs). The aim of this study was to prove the stimulating effect of the oral consumption of EFLA®894 Echinacea purpurea dried pressed juice on human immunity.

While Echinacea is mostly studied for non-specific innate immunity, this study particularly focused on adaptive cell-mediated immunity.

Study design

This was a randomized, placebo-controlled, double-blind, and parallel group clinical study conducted in Japan in 2011. Twenty-two healthy adult volunteers, 20 to 70 years old, participated in the study. Selected participants had a weakened immunity as indicated by a constant feeling of daily fatigue and an immunity score < 22, assessed as described below during an health check-up. They were randomly assigned to either the Echinacea or placebo group. Each participant in the Echinacea group ingested daily a preparation containing 500 mg of EFLA®894, those in the placebo group a matching placebo product, during 3 weeks. Several hematopoietic and immunological parameters were measured at study start and after 1 and 3 weeks of treatment. As a comprehensive tool to assess immunity, a scoring method was determined that standardizes various immunological parameters, combines them and expresses the immune status of individuals as a simple numeral, termed score of immunological vigor (SIV).

The SIV includes several subpopulations of circulating lymphocytes, especially T-cells, and NK cells activity as core indices for the immune status of healthy people with declined immune function. Additionally, a questionnaire on self-rated health was included. Safety was evaluated based on monitoring of adverse events and routine medical check-up including laboratory examinations of the blood and urinalysis.

Results

Immunomodulatory effects

Echinacea improved the immunological status of study participants, as shown by an increased Score of Immunological Vigor (SIV) after three weeks of treatment. The SIV significantly improved only in the Echinacea group, while it remained unchanged in the placebo group, as shown in Fig.1.



Fig. 1: Results of the score of immunological vigor (SIV) for both treatments at study start, week 1 and week 3. (*p < 0.05, significant differences between groups were based on statistical analyses by Student's t-test).

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Among the 8 parameters included in the score, 5 items tested increased with Echinacea. On the other hand, with placebo the values measured for these parameters tended to decrease or remain unchanged, explaining why the immunity score did not change.

A significant improvement of the following measures of immune function was observed with Echinacea compared with placebo (Fig.2): The number of lymphocytes, the CD4+ T cell count and the memory T cells count. Additionally, the number of T cells increased with Echinacea, when compared to placebo, with borderline significance.

However, the number of NK cells and its activity decreased in both groups, and the number of B cells did not show any significant changes.

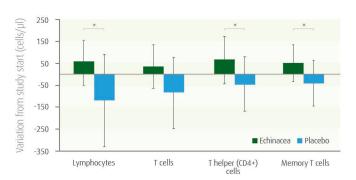


Fig. 2: Mean change from study start to study end (3 weeks) of some parameters of immune function (lymphocytes, T cells, T helper (CD4+) cells and memory T cells counts) in both groups (Mean values \pm SD; *p < 0.05, significant differences between groups were based on statistical analyses by Student's t-test).

Measure of subjective health

In an attempt to relate the objective measure of improved immunity to a subjective assessment of better health and fatigue, a VAS-questionnaire for the self-rating of perceived health status was included in this study. Echinacea resulted in a reduced sense of subjective stress response and in improved self-rated health. Most of the topics of the questionnaire were judged as improved by the volunteers taking Echinacea. Reduced mental stress and a better feeling of recovery from fatigue were noticed first, as soon as 1 week after start of intake.

Safety and tolerability

All safety parameters were within normal ranges at baseline and at study end in both groups (not shown). No adverse events were reported during the study.

Conclusion

The findings of this study show that EFLA®894 Echinacea purp. dried pressed juice could improve the immune function, especially that mediated by T-cells, in healthy people with a constant feeling of fatigue, indicating reduced immunity. This improvement correlated with a better self-estimated sense of health.

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