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Throat Spray With Blended Essential Oils Promotes Healthy Lung Function Among Women: A Randomized, Double Blinded, Placebo Controlled Clinical Trial

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Abstract

Introduction: There are numerous internal and external environmental threats to lung health. Compromised respiratory health can affect a person's quality of life. This clinical trial evaluated the effects of Teramune Bronchus on lung health among healthy adult women.

Methods: The participants were women, aged 18 - 60 years old (n = 35). They sprayed either the proprietary essential oil based blended product (Teramune Bronchus) or a placebo into their throats 4-6 times per day during waking hours for 3 days. There was a baseline survey before using the spray and then follow-up data were collected at the end of day 3. The three primary outcomes for this study include a total bronchial symptom score, the chest domain in the Wisconsin Upper Respiratory Symptom Scale (WURSS), and subjective bronchial wellbeing.

Results: On day 3, the bronchial health of the participants who received the throat spray had significantly larger change scores when compared those with the placebo spray. All chest-related symptoms were resolved fully by the end of the trial for the participants who used Teramune. Participants using the intervention were almost twice as likely to say they felt better and believed the product helped them achieve lung health.

Conclusion: This study provides evidence that the use of Teramune Bronchus supports respiratory health. Teramune Bronchus boosts respiratory health among healthy women through the use of plant-based essential oils.

Keywords

bronchial wellness, respiratory health, aromatherapy, essential oils, clinical trial, lung health

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Introductionn

Background

The lungs are the primary component of the respiratory system, which contains the organs and tissues responsible for the breathing process.[1,2] The lungs, which are a critical component of wellness, are under near constant attack from a myriad of factors. Air pollution, both indoors and outdoors, infectious disease, chronic respiratory disease, environmental carbon, and the aging process are all threats to lung health.[3,4] The lungs are also the target of many microbes with pandemic potential, including the SARS-CoV and then SARS-CoV-2 virus which caused the COVID-19 pandemic.[5,6]

Prevention of lung-related health concerns consists primarily of lifestyle factors, avoidance of environmental exposures such as smoking and pollution, and public health measures such as clean air and water.[7,8] Poor lung health is associated with an increased risk of respiratory infections, which often require medical intervention.[9] When patients arrive in the emergency room with respiratory complaints, antimicrobials are prescribed between 20-35% of the time, which is associated with an increase in drug resistance.[10] Compromised respiratory health can also adversely affect overall quality of life.[11]

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Supporting respiratory health is essential for both individual and public health.

There are few studies of plant-based supplements that have been shown to support respiratory health.[12,13] Some individual plant extracts have been found to boost respiratory health.[14–16] However, the body of evidence is small and combined blends of these ingredients have yet to be studied.

Objectives

There is little known on how consuming essential oils in the form of a throat spray performs on respiratory illness in otherwise healthy adults. The purpose of this study was to evaluate the effects of Teramune Bronchus, a proprietary essential oil based formula throat spray, on lung health, as compared to a placebo group. This product is marketed in the United States as a dietary supplement for respiratory health. This study is reported using the CONSORT checklist for reporting clinical trials with the Herbal Medicinal Interventions extension.[17,18]

Methods

Trial Design

This was a randomized, double blind, placebo controlled, clinical trial evaluating the effects of Teramune Bronchus on lung health among otherwise healthy adult women aged 18-60. Participants were randomized using block randomization with a group size of 3. The intervention group used the Teramune Bronchus spray regularly for 3 days while the placebo group used an inactive spray for 3 days.

Participants

Participants were eligible to participate if they met the following inclusion criteria: otherwise healthy adult women aged 18 through 60 years. To be included in the study, volunteers were required to be currently experiencing routine respiratory symptoms without being in a diseased state. Respiratory function differs by sex, and women are underrepresented in the clinical literature, so this study was powered to focus exclusively on women.[19]

Exclusion criteria included: underlying chronic lung conditions such as asthma. Women who were pregnant or attempting to achieve a pregnancy were excluded, as were women who were breastfeeding. Tobacco use in the home was also an exclusion criterion. Participants with a known COVID-19 diagnosis were excluded. Additionally, the baseline assessments collected prior to the intervention were used to distinguish between participants in a diseased state and those with routine, normal respiratory symptoms. Participants who had scores indicating a diseased state at baseline were excluded from the intervention as the purpose of this study is to evaluate the throat spray as a dietary supplement for promoting healthy lung functioning.

All participants were recruited from a private medical practice in middle Tennessee. Participants visited the medical practice, either as part of a routine wellness visit or a response to a call for participants, and were screened by the participating licensed medical providers. If they met the inclusion criteria and provided informed consent, they were given the materials and instructions required for participation. The medical providers maintained records linking the identification numbers with the participant's medical records. In the event of an adverse event, the medical providers were to use these records to request unmasking of the group assignment from the researchers. However, no participants experienced any adverse events, so the assignments were not revealed to the medical providers until after the study.

Intervention

The product (Teramune Bronchus) contains a blend of essential oils extracted from multiple plants including: pine *(Pinus sylvestris)*, eucalyptus *(Eucalyptus polybractea cineol) & (Eucalyptus citriodora)*, ravensara *(Ravensara (ou ravintsara) aromatica)*, cypress *(Cupressus sempervirens)*, hyssop *(Hyssopus officinalis)*, thyme (*Thymus vulgaris thymoliferum)*, sage *(Salvia sclarea)*, dill *(Anethum graveolens)*, rosemary *(Rosmarinus officinalis camphoripherum)*, and bay laurel *(Laurus nobilis)*. The essential oil blend was dispersed within a carrier formulation which includes apple cider vinegar, aloe vera gel, olive oil, and almond extract. The plant extracts were sourced from a laboratory in France and formulated by Teramune, which is based in San Diego, CA. The placebo contained the carrier formulation without the essential oils.

Both the active product and the placebo were delivered in a 15ml glass bottle with a spray top labeled only with the participant ID. Dosing for an otherwise healthy adult is 0.5-1.0mls/day delivered in 4-6 doses throughout waking hours. Participants were instructed to ingest the formula by pumping 1 spray directly into the back of their mouth every 4-6 waking hours for the entire 3 day intervention. This allows the participant to breathe the aroma while ingesting the supplement and ensures they do not accidentally ingest more than the designated amount.

Prior to ingesting the formula, baseline data were collected on day 1. Participants then immediately began using the spray and continued to use it during waking hours over the next 3 days. Follow-up data were collected after 3 days. At the end of the intervention period, participants were debriefed by the research team. Adherence to the protocol was monitored throughout the study through regular contact with each participant via phone and email. Participants who did not adhere to the entire protocol were removed from the final data analysis.

Outcome Measures

Each outcome was measured using clinically validated instruments which allow for self reporting of signs and symptoms reflective of respiratory health. The three primary outcomes for this study include bronchial symptoms, the chest domain in the Wisconsin Upper Respiratory Symptom Scale (WURSS), and subjective bronchial well-being. These outcomes were measured using dichotomous symptom scores indicating ten state symptoms, the WURSS, and subjective yes/no outcome-related questions. Because this supplement is intended to improve lung health, the primary outcome is the chest domain.

Wisconsin Upper Respiratory Symptom Survey

The WURSS chest domain was used to assess bronchial health and the entire scale was used to identify patients who should be excluded for being in a diseased state. The WURSS is a validated instrument with internal consistency scores ranging from 0.76 to 0.96[20] &.[21] It is also highly correlated with the Jackson Symptom Scale ($R = 0.85$).[22]

The complete instrument contains 44 questions which are ranked on a Likert scale of 0-7, with 0 indicating "do not have" and 7 indicating "severe." These data are separated into ten distinct outcomes, referred to

as domains. WURSS domains include throat, nasal, sinus, ears, sweats, aches, cough, chest, fatigue, and activity. Because this supplement is intended to improve lung health, the primary outcome is the chest domain.

Other Measures

Secondary outcome measures include bronchial symptoms. These were measured through a series of dichotomous scores reflecting current bronchial symptoms. Symptoms measured include: dry, tickly, irritated, swollen, inflamed, burning, hurts to swallow, painful to talk, and "like I swallowed broken glass."

Data collection also included information about the use of medications to treat respiratory symptoms, including dietary supplements, over the counter drugs, and pharmaceutical treatments. These data were used as control variables to ensure differences between groups can be attributed to the supplement and not other factors.

Sample Size

A power analysis was conducted based on the minimum required to identify a very large effect ($d = 1.0$) for a two-sample t-test powered at.8 with.05 significance. This produced a need for 36 total participants evenly divided between the groups. To allow for exclusion of diseased participants and loss to follow-up, a minimum of 60 participants would be recruited.

Randomization & Blinding

Participants were randomized using block randomization with a block size of 3. Participant identification numbers were assigned following this block sequence.

To achieve double blinding of the participants and the medical providers, the products were labeled by the research team with participant identification numbers. Placebo and intervention throat sprays were identical in packaging and appearance. The medical practice did not have access to the product labeling code, ensuring concealment of the actual contents of the products.

The success of randomization was evaluated using t-tests for continuous demographic variables and chi squared analysis for categorical demographic variables. The groups were not statistically significant on any demographic variables.

Ethics & Regulatory Authorization

The study was conducted in accordance with the Declaration of Helsinki and adhered to Good Clinical Practice guidelines.[25] Ethical approval for the study and the informed consent documents were obtained. Approval for the protocol was obtained by a central IRB prior to the recruitment of the first participant. The trial was also registered at ClinicalTrials.gov, NCT04368169. All participants provided written informed consent prior to any intervention procedures.

Statistical Methods

The primary endpoint was evaluated using 2-tailed independent samples t-tests of change scores. Change scores were created by subtracting the 3-day scores from baseline scores. Comparison of baseline scores between groups using t-tests revealed no significant differences between the two groups at the start of the trial. The total change scores between groups were evaluated using t-tests with a p-value of <.05 being considered significant. Participants were evaluated on an intent-to-treat basis. All statistical analyses were performed using Stata v16.

Results

Recruitment

Participants were recruited from May 2020 through July 2020. Qualifying participants visited the associated medical office to learn about the study and to provide informed consent. Participants who provided consent were given the study materials and an orientation packet which contained instructions, primary investigator contact information, and copies of the consent forms they signed. Participants provided baseline data through a secure online portal and then provided follow-up data through the same portal 3 days later. Those who did not provide follow-up data were contacted through phone and email.

A total of 71 participants were recruited. After screening for inclusion criteria, 25 participants did not qualify. This produced 46 qualified participants in the trial, 23 allocated to the intervention group and 23 allocated to the placebo group. Through the intervention period, 11 were disqualified for developing documented illness, or they withdrew from the trial. More patients in the treatment group discontinued the study (n = 8) than in the placebo group (n = 3). Reasons for discontinuation included disliking the taste of the product, discontinuation of symptoms, and forgetting study instructions. A total of 35 participants produced data which qualified for the statistical analysis (n = 35). (See Image 1: Flow Chart).

Baseline Data

Baseline demographic data included age range, weight, height, race, income range, presence of comorbidities, and current medications / dietary supplements. Participants were predominantly white. Height and weight were approximately normally distributed.

Primary Outcomes

Outcome 1: Bronchial Symptoms

After confirming assumptions of equality of variance, an independent samples t-test was conducted to evaluate the impact of the throat spray on bronchial health. Bronchial symptom scores were measured on a scale of 0-10 with 0 indicating no symptoms at all, while 10 indicated the presence of every symptom measured. At the start of the study, bronchial symptom scores were 3.20 (SD = 2.40) in the placebo group and 4.73 (SD = 2.94) in the Teramune group.

On day 3, the participants who received the Teramune Bronchus spray had significantly larger change scores ($M = -3.20,\ SD = 2.34$) when compared those with the placebo spray ($M = -1.40,\ SD = 2.34$), $t(33) = 2.33$, $p = .026$, with a Cohen's d of.79. See Table 1.

Additional Analysis

To evaluate the change from baseline to day 3, an additional t-test was conducted on scores within the Teramune group. A

statistically significant decrease was identified in scores from baseline (M = 4.73, SD = 2.94) to day 3 (M = 1.53, SD = 2.13), t(14) = 4.49, $p = <.001$ (two-tailed). The mean decrease in scores was 3.2, with a 95% confidence interval ranging from 1.91 to 4.49. The use of Teramune Bronchus was associated with a reduction of an average of 3 symptoms per participant during the 3-day period.

Outcome 2: WURSS Chest Domain

Lung health scores were measured using the chest domain of the WURSS, which measures chest congestion, chest tightness, and chest heaviness. Higher scores indicate more severe symptoms. After confirming assumptions of equality of variance, an independent samples t-test was conducted on change scores to evaluate the impact of the throat spray on chest health.

At the start of the study, mean chest domain scores were 0.63 (SD = 1.42) in the placebo group and 1.27 (SD = 1.98) in the Teramune group. On day 3, the participants who received the Teramune Bronchus spray had significantly larger change scores ($M = -1.27$, $SD = 1.98$) when compared participants with the placebo spray ($M = -0.26$, $SD = 1.48$), t(32) = 2.58, $p = .015$, with a Cohen's d of.89. See Table 1.

Additional Analysis

To evaluate the size of the change in the Teramune group, a t-test was performed comparing the baseline scores to day 3. In the Teramune group, there was a statistically significant decrease in scores from baseline (M = 1.27, SD = 1.98) to day 3 (M = 0.00, SD = 0.00), t(14) = 2.47, $p = .027$ (two-tailed). For those taking Teramune, all chest-related symptoms were resolved fully by the end of the trial. The mean decrease in scores was 1.27, with a 95% confidence interval ranging from 0.17 to 2.36.

Conversely, in the placebo group, there were no significant differences between baseline (M = 0.63, SD = 1.42) and day 3 (M = 0.89, SD = 2.62), t(19) = −0.77, $p = .45$ (two-tailed). Improvements in lung function in the Teramune group were substantially larger than those in the placebo group.

Outcome 3: Subjective Bronchial Health

Subjective bronchial health was measured using three dichotomous questions about the participant's belief that the spray improved their lung health, shortened the duration of symptoms, and whether or not they would use it for lung health in the future. A score of 0 indicates they answered no to all three questions, while a score of 3 indicates they answered yes to all three.

Table 1. Differences Between Change Scores in the Intervention and Placebo Groups.

Measure	Teramune Mean (SD)	Placebo Mean (SD)	t(33)	*P* value
Bronchial Symptoms	−3.20 (2.34)	−1.40 (2.34)	2.33	**.026**
Chest Domain	−1.27 (1.98)	−0.26 (1.48)	2.58	**.015**

Participants who received the Teramune Bronchus spray were significantly more likely to indicate improvements in lung function ($M = 2.73$, $SD = 0.80$) when compared to participants with the placebo spray ($M = 1.55$, $SD = 1.29$), t(31) = −3.07, $p = .004$, with a Cohen's d of 1.07. Participants who used the Teramune Bronchus spray were almost twice as likely to say they felt better and believed the product helped them achieve lung health. See Table 2.

Discussion

Safety

Participants were monitored for adverse events throughout the trial. No adverse events were identified in either group. In this trial, Teramune Bronchus was found to safely support respiratory health, and does not pose a significant risk of adverse effects.

Limitations

This study was conducted during a respiratory virus-induced pandemic. As a result, individuals around the globe were boosting lung and immune health through prevention measures such as face masks, increased hand washing, and limited exposure to others. The effects of Teramune on lung health may be larger than identified in this trial during a time when individuals have more frequent exposure to routine respiratory irritants.

Additionally, this study was limited to otherwise healthy adult women. This reflects the population most likely to supplement with plant-based supplements.[23,24] Future studies should evaluate the impact of Teramune Bronchus on children and other vulnerable populations for increased generalizability.

Table 2. Subjective Bronchial Health Scores in Intervention and Placebo Groups.

Measure	Teramune Mean (SD)	Placebo Mean (SD)	t(30)	*P* value
Subjective Bronchial Health	2.73 (0.80)	1.55 (1.29)	−3.07	**.004**

Table 1. Age and Race Frequencies (n = 35).

Measure	Total	%
Age Range		
1960-1969	3	8.57
1970-1979	8	22.85
1980-1989	13	37.14
1990-1999	11	31.42
Race		
White	28	80.00
Black	0	0
Hispanic	3	8.57
Other	4	11.43

Interpretation

This study provides evidence that the use of Teramune Bronchus supports respiratory health, specifically by promoting bronchial and lung function. At the end of day 3, the participants who received Teramune Bronchus spray were significantly healthier on measures of bronchial wellness, lung health (as measured through the WURSS chest domain), and subjective bronchial health, as compared to the placebo group. Within the Teramune group, chest function was fully restored by the end of the trial, while those in the placebo group experienced no improvement during the three days of the trial.

Generalizability

In an adult female population, which demographically resembles the patient most likely to use natural products, Teramune Bronchus spray was found to substantially boost lung health. Across all measures, participants in the placebo group experienced increases in symptoms, while those in the Teramune group experienced maintenance of bronchial health and reduction in the total symptoms.

Overall Evidence

Teramune Bronchus was found to substantially boost respiratory health in otherwise healthy women experiencing respiratory symptoms.The use of Teramune was associated with 67.6% fewer bronchial symptoms after 3 days of use and complete resolution of chest-related symptoms. These benefits offer substantial overall respiratory support to women who are experiencing routine lung and chest-related symptoms.

Additionally, participants in the Teramune group were nearly twice as likely to report that they feel better and believe the product helped them achieve lung health. This is noteworthy as many dietary supplements improve wellbeing but with an effect too small to be recognized by patients.

Teramune Bronchus boosts respiratory health among healthy women through the use of plant-based essential oils. Future research should evaluate the potential for these effects to be replicated in other populations.

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Christy Y Hires, MPH: Methodology; Writing – Original & Editing
Elizabeth Dunne, RDN: Investigation; Writing – Review & Editing
Lindsey Keenan, RDN: Conceptualization; Writing – Review & Editing; Visualization

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