Protocol Date June 21, 2018

Study Protocol Title:
Molekule for allergic rhinitis/asthma
Molekule for allergic rhinitis/asthma

Background:

In the United States, the incidence of respiratory allergies and asthma are increasing, with 10-40% of the population suffering from allergies 1 and 8% suffering from asthma2. The direct and indirect health costs and decrement in quality of life from these illnesses are substantial2,3. While these symptoms are typically attributed to aeroallergens, there are particulate matter and volatile organic compounds (VOCs) that act as irritants that can also evoke symptoms. Local air filtration has shown some ability to decrease allergen counts in the air and thus improve the symptoms experienced by allergy and asthma sufferers under certain conditions4. However, to date the efficacy of a comprehensive air purification system, particularly with high efficiency particulate air (HEPA) filtration, as a sole intervention modality has been equivocal and the extent of air filtration remains suboptimal.

Photo-electrochemical oxidation (PECO) is a revolutionary new technology for providing an air purification solution. In addition to physical filtration, a photo-electrochemical reaction takes place on the surface of a nano-coated filter leading to the oxidation of organic matter. These processes allow for the destruction of organic material 1000 times smaller than what a HEPA filter can capture5,6. Thus, PECO not only removes but can also efficiently destroy organic matter, bacteria, viruses, mold, and VOCs converting them into their trace elements 7.

Specific Goals/Objectives:

Primary Objective: To assess the efficacy of the portable Molekule air purifier in reducing symptoms from allergic rhinitis and asthma.

Hypothesis: The portable Molekule air purifier will significantly improve allergy and asthma symptom scores in patients with allergic rhinitis and asthma.

Study Design:

• Randomized double blinded placebo, controlled trial for participants using the Molekule air purifier or placebo unit for a total of 4 weeks. The portable unit will be placed at the participants bedside and will be running continuously. Screening survey for eligibility will take place and unit will be shipped and ready for use within 1 week. Device use will take place for 4 weeks and then there will be an exit survey. Primary endpoint is change in CARAT scores. Unit should be running >18 hours per day including at night time in the participant bedroom

Patient Selection:

Inclusion Criteria:
• Chronic allergic rhinitis and/or conjunctivitis by history
• History of adult asthma requiring medications now or in the past
• Age ≥18
• CARAT score less than 24

Exclusion Criteria:
• Use of systemic corticosteroids within 14 days of study initiation
• Treatment with biologic agents or allergen immunotherapy
• Treatment with other immunomodulators (cyclosporine, azathioprine, hydroxychloroquine, etc)
**Study Endpoints**

**Primary Endpoints:**
- CARAT scores (see survey below)

**Secondary Endpoints/exploratory:**
- Upper airway scores per CARAT
- Lower airway scores per CARAT
- Change in allergy medication use
- Change in asthma medication use
- Asthma exacerbations requiring clinic or ER visits
- Compliance of air purifier use

**Statistical Analysis:**

A sample size of 110 subjects, 55 in each arm, is sufficient to detect a clinically important difference of 3.5 between groups assuming a standard deviation of 6.43 using a two-tailed t-test of difference between means with 80% power and a 5% level of significance.

SigmaStat 4.0


Software: SigmaStat V4.0

**Additional items:**

1) Obtain IRB approval-2-4 weeks

2) Manufacture placebo and active units-8 weeks (I am estimating that we will be able to have approximately 60 units (30 + 30) made for this purpose)

3) Screen participants from Molekule mailing list, begin enrollment and ship units

4) Those randomized to placebo will be contacted at the conclusion of the study and will be able to test the units (data not planned to be collected)

**References:**


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**Control of Allergic Rhinitis and Asthma Test**

3-05-2018

During the last 4 weeks, because of your asthma/rhinitis/allergy, how many times, on average, did you experience:

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Up to 2 days per week</th>
<th>More than 2 days per week</th>
<th>Almost every day or every day</th>
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</thead>
<tbody>
<tr>
<td>1. Blocked nose?</td>
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<tr>
<td>2. Sneezing?</td>
<td></td>
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<td>3. Itchy nose?</td>
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<td>4. Runny nose?</td>
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<td>5. Shortness of breath/dyspnoea?</td>
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<td>6. Wheezing in the chest?</td>
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<td>7. Chest tightness upon physical exercise?</td>
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<td>8. Tiredness/limitations in doing daily tasks?</td>
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<td>9. Wake up during the night because of your asthma/rhinitis/allergy?</td>
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</table>

During the last 4 weeks, because of your asthma/rhinitis/allergy, how many times did you have to:

<table>
<thead>
<tr>
<th></th>
<th>I am not taking any medicines</th>
<th>Never</th>
<th>Less than 7 days</th>
<th>7 or more days</th>
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<tbody>
<tr>
<td>10. Increase the use of your medications?</td>
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* All questions are mandatory

Total Score: 0

Score of the upper airway (item 1-4): 0

Score of the lower airway (item 5-10): 0

Scores higher than 24 indicate good disease control

Controlled if score is >0

Controlled if score is ≤15