

### **In an investigator initiated<sup>\*1</sup> clinical trial, Plasmacluster Ion technology<sup>\*2</sup> reduced airway inflammation in pediatric patients with mild<sup>\*3</sup> to moderate<sup>\*4</sup> atopic asthma**

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In investigator initiated clinical research<sup>\*5</sup> commissioned by Sharp, results were obtained in exploratory analysis<sup>\*6</sup> indicating that Plasmacluster Ion technology reduced the level of airway inflammation in pediatric patients with mild to moderate atopic asthma (FeNO<sup>\*7</sup> value less than 90).

Sharp commissioned The University of Tokyo Hospital, Clinical Research Support Center, to conduct this research, and provided special Plasmacluster Ion generators for use in the clinical study. Mr. Yasuo Ohashi, Emeritus Professor of The University of Tokyo, and also a Professor on the Faculty of Science and Engineering at Chuo University, assumed responsibility for data analysis and design of the clinical research. In addition, Mr. Toshio Katsunuma, Associate Professor, Department of Pediatrics, The Jikei University Daisan Hospital, served as coordinator of trial sites and was in charge of recruiting subjects as well as testing and measurement.

This clinical study targeted 130 pediatric patients with mild to moderate atopic asthma. In this clinical research study, special Plasmacluster Ion generators producing an ion concentration of 100,000 ions/cm<sup>3</sup> were set up in the home in two rooms where the subjects spent long periods of time selected from among the bedroom, living room, and children's room (nursery). Observations were made for eight weeks before and eight weeks after activation of the Plasmacluster Ion generators using the individual randomized crossover double-blind comparison protocol<sup>\*8</sup>.

This clinical study found that the level of airway inflammation in children with atopic asthma was reduced, and that Plasmacluster Ion technology<sup>\*2</sup> will contribute to human health in an actual living environment.

Dust mite allergens are one of the major antigens causing asthma. Thus far, Sharp has proven that Plasmacluster Ions have an inhibitory effect against airborne dust mite allergens<sup>\*9</sup>, which are in dust mite fecal pellets and body fragments, and also went on to elucidate the mechanism underlying the inhibition of these allergens<sup>\*10</sup>.

In the future, Sharp will push ahead with further development of Plasmacluster Ion technology<sup>\*2</sup> and continue to prove its efficacy with the aim of creating a healthy environment.

It should also be noted that the details of this clinical study are scheduled to be presented by the research group (Professors Yasuo Ohashi and Toshio Katsunuma) at the 51<sup>st</sup> Annual Meeting of the Japanese Society of Pediatric Allergy and Clinical Immunology to be held beginning November 8, 2014.

**Comments by Mr. Yasuo Ohashi, Emeritus Professor of The University of Tokyo, and Professor, Faculty of Science and Engineering, Chuo University**

This double-blind randomized clinical study of a home appliance technology for pediatric asthma patients is unique, and I can say that there is a strong trailblazing spirit in this current study. The findings indicate that there is a potential for Plasmacluster Ion technology to reduce the level of airway inflammation in pediatric patients with mild or moderate atopic asthma. This study will contribute to the development and deployment of the methodology, and I think it suggests that Plasmacluster Ion technology will make a difference in the world.

**Comments of Mr. Toshio Katsunuma, Associate Professor, Department of Pediatrics, The Jikei University Daisan Hospital**

Plasmacluster Ion technology is not a drug nor even medical equipment. This technology shows the potential to suppress respiratory tract inflammation in children with mild to moderate asthma and to improve their respiratory function, and I think this is highly significant with respect to undertaking long-term care of asthmatic children.

It is my hope that this data will bring good news to children with asthma and to their families.

\*1 The University of Tokyo Hospital, Clinical Research Support Center was commissioned to conduct this research and provide research support.

\*2 Plasmacluster is a registered trademark of Sharp Corporation.

\*3 Mild asthma is defined as having coughing or wheezing symptoms more than once a month but not more than once a week. At times, it may be accompanied by difficulty in breathing. Duration is short, and interference in daily life is minimal (based on the Japanese Pediatric Guideline for the Treatment and Management of Asthma 2012).

- \*4 Moderate asthma is defined as having coughing or wheezing symptoms at least once week, but not continuing on a daily basis. On occasion, it may manifest as a moderate to severe attack, and disrupts sleep and/or normal daily activities (based on the Pediatric Guideline for the Treatment and Management of Asthma 2012).
- \*5 The University of Tokyo Hospital, Clinical Research Support Center, the organization contracted to conduct this research, is independent of Sharp Corporation and was commissioned to provide support in the form of planning of clinical research to implementation and reporting.
- \*6 Prior to the start of the study, it was determined that the analysis would cover all subjects. However, under this criteria, it was not possible to verify the effects of Plasmacluster Ion technology, most likely because subjects suffering from high levels of inflammation were included. By limiting the range of subjects, an improvement in respiratory function was found, for which expectations were initially low.
- \*7 Fractional exhaled nitric oxide, a measure of the concentration of NO in exhaled breath. An indicator of the level of airway inflammation.
- \*8 A protocol for clinical trials designed to objectively examine the efficacy of investigational new drugs.
- \*9 Announced on September 3, 2003.
- \*10 Announced on July 21, 2006.

## **Overview of Clinical Research**

### Participants

130 asthma patients between the ages of 6 and 15 years, with mild\*<sup>3</sup> or moderate\*<sup>4</sup> cases of atopy

### Research design

Subjects were randomly split into two groups, and ion generators made specifically for clinical research were placed in their homes.

The individually randomized double-blind crossover comparison protocol\*<sup>8</sup> was used.

### Period

August 9, 2013 to May 30, 2014

### Assessment items

Change in FeNO value\*<sup>7</sup>, change in asthma symptoms, change in respiratory function value, QOL (quality of life)\*<sup>11</sup>

### Ion density of ion generating device made specifically for clinical research

Maximum ion density of approximately 100,000 ions/cm<sup>3</sup>

## Test results

- For subjects who had an initial FeNO value\*<sup>7</sup> of 90 or less, compared to the placebo device\*<sup>12</sup>, use of the ion generating device made specifically for clinical research resulted in a decrease (an improvement) in the FeNO value\*<sup>7</sup>, which is one of the indicators of inflammation.
- For subjects who had an initial FeNO value\*<sup>7</sup> of 90 or less, compared to the placebo device\*<sup>12</sup>, use of the ion generating device made specifically for clinical research resulted in an increase (an improvement) in V<sub>25</sub>\*<sup>13</sup>, which is one of the indicators showing constriction of peripheral airways of lungs.
- Compared to pre-test values, by the end of the test there was a decrease (an improvement) in the QOL score.

\*11 QOL: Like the name suggests, Quality of Life is an assessment of the quality of a person's day-to-day living conditions.

\*12 Placebo device: A device that disperses air without Plasmacluster Ions.

\*13 An indicator of the state of the airways (in particular the peripheral airways of lungs), one of the factors of respiratory functions.

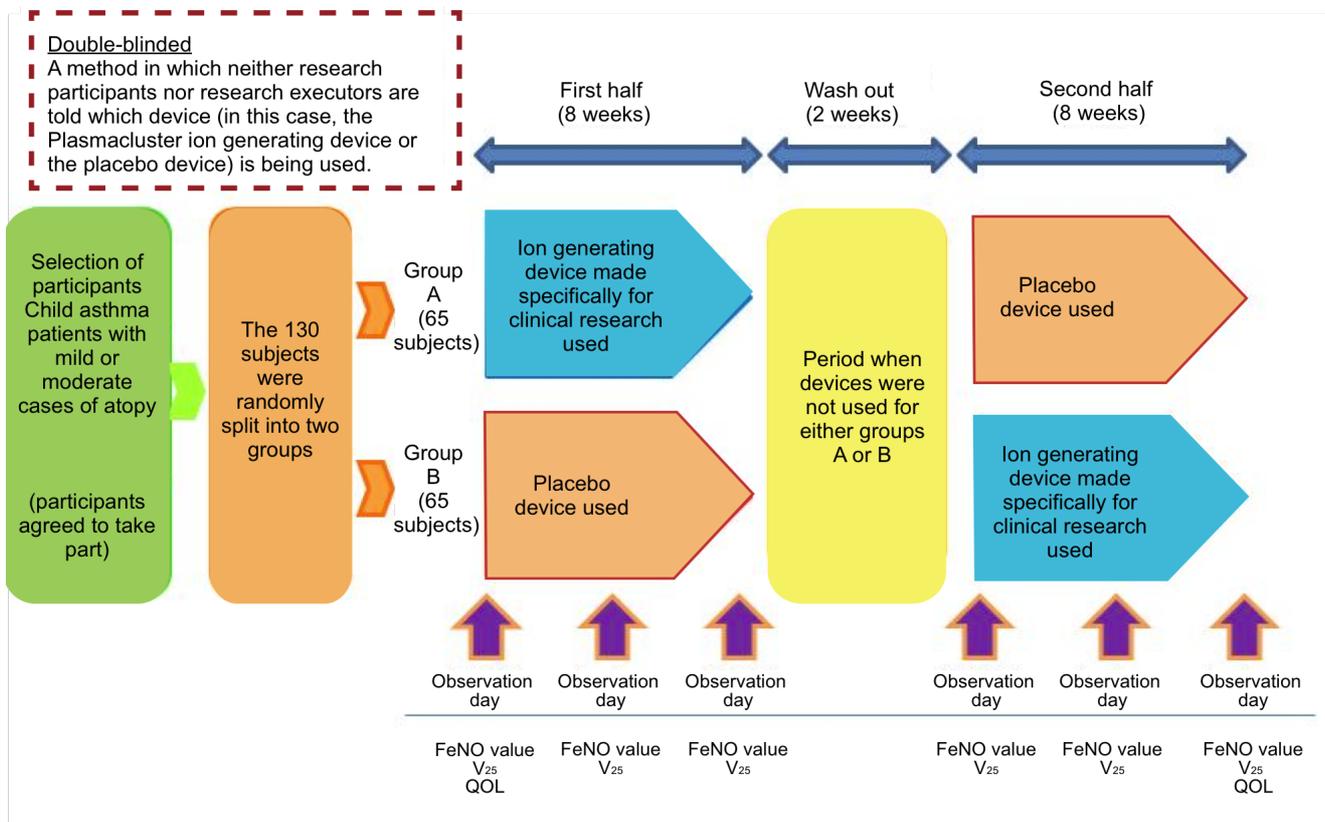


Diagram of research design