



CLINICAL TRIAL WHITE PAPER

PHYSIOLOGIC EFFECTS OF THE RESPIN 11 DEVICE FOR OPTIMAL HIGH FREQUENCY CHEST WALL OSCILLATION



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INFORMATION

DEVICE

RespIn 11 Bronchial Clearance System.

LOCATION OF TRIAL

USA

University of South Florida - Division of Pulmonary and Critical Care Medicine.

FRANCE

Centre Hospitalière de Cannes.

Centre Hospitalière de Grasse.

INVESTIGATORS

Brice Taylor MD (USA).

CO-PRINCIPAL INVESTIGATORS.

Doctor Christophe Perrin (France).

Doctor Micheline Gomez Figueredo (France).

Doctor David Solomon (USA).

Doctor Alan Goldman (USA).

SPONSOR

RespInnovation SAS, 611, chemin de l'Adrech, 83440 SEILLANS France.

STUDY TYPE

Open label, prospective, clinical effect trial.

SUBJECTS

30 patients

STUDY DURATION

2 years.

DURATION OF SUBJECT PARTICIPATION

1 week.

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PRODUCT NAME: RESPIN 11 BRONCHIAL CLEARANCE SYSTEM

RespInnovation SAS has designed and conceptualized a 2nd generation 'focused pulsation' High Frequency Chest Wall Oscillation device capable of aiding in airway clearance of pulmonary secretions in a much wider range of patients and clinical conditions than existing devices.

The Respin 11 device benefits from an innovative approach to the 30 year old concept of High Frequency Chest Wall Oscillation (HFCWO) therapy and makes use of modern technologies and materials to produce a more comfortable and effective therapy delivery system which:

- is more flexible and able to direct pulsations to selected parts of the patient's thorax,
- gives increased control of therapy to the treating clinician, and
- can be safely used with a wider range of patients and clinical conditions.

In addition, the Respin 11 operates at a very low background pressure, which:

- is beneficial to patients on both a therapeutic and comfort level, and,
- does not cause important unwanted changes to various patient physiological parameters.

The Respin 11 works on an innovative, patented concept for the creation and delivery of focused therapeutic HFCWO pulsations using a patented system of valves, electronic controls, and targeted pressure pistons which delivers pulsations directly to targeted areas of the patient's thorax exactly where most required and most beneficial. Test results show that the Respin 11 system is much more comfortable for the patient than existing devices due to a low background pressure and a massage-like effect created by the pressure pistons being sequentially actioned.

SUMMARY OF FINDINGS FROM SAFETY TESTS HAVING CLINICAL SIGNIFICANCE

An initial safety evaluation of the Respin 11 device versus The Vest (Hill-Rom) was carried out in the summer of 2011 in Rome and March 2012. Eight and then 14 study subjects underwent treatment with both devices for periods of 15 minutes each. This study was carried out under medical supervision.

During a pilot study with the Respin 11 device in eight normal patients:

- Patients felt none of the negative effects associated with existing 1st generation HFCWO devices such as: dizziness, chest tightness, breathing difficulty, difficulty swallowing, or sensations of panic and suffocation.
- Patients had a low level of clinically measurable impact on the physiological state of the patient during therapy sessions with no measured adverse effects on heart rate, blood pressure, ECG, etc.; unlike the existing devices which in some patients cause significant physiological changes.

Safety and test subject feedback during the pilot study was also unanimous in indicating preference for the Respin 11 jacket (patient satisfaction surveys during preliminary testing reported)

- The Respin 11 jacket was more comfortable and easy to use than the existing devices,
- The Respin 11 was more like a 15-minute therapeutic massage than a 15-minute difficult therapy session.

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With the RespIn 11 device, none of the subjects demonstrated significant elevations of systolic or diastolic blood pressure. None of the subjects experienced significant changes in HR or SaO₂.

With The Vest device, the blood pressure elevation was 3 – 12% in the systolic blood pressure and 3 – 18% in the diastolic blood pressure. The average increase in HR was 7% [range 0 – 25%] and there was no change in SaO₂.

SPONSOR / RATIONALE & OBJECTIVES

SPONSOR INFORMATION

RespInnovation SAS designs, develops and markets a second generation of medical device technology based on High Frequency Chest Wall Oscillation (HFCWO) Therapy for the treatment of many diseases with chronic obstruction of the lungs, damage to the bronchi that result in chronic infection and production of significant amounts of exudative infectious mucus that must be eliminated from the lungs and bronchi, or neurodegenerative diseases that prevent patients from effectively clearing their lungs of even normal amounts of secretions. This device is very effective to release the lung airways of mucus and help patients expectorate. It is suitable for home care and hospital

TRIAL OBJECTIVES AND PURPOSE

HFCWO Therapy has been demonstrated as a means to help clear the lungs of secretions in patients with different types of lungs disease (e.g., chronic obstructive pulmonary disease, cystic fibrosis, bronchiectasis) or neurodegenerative diseases that result in patients being unable to clear secretions from the lungs (e.g., Amyotrophic lateral sclerosis, Parkinson's disease, Alzheimer's disease, etc.).

The currently available HFCWO devices require a circumferential compression of the chest wall and thorax that can have significant physiologic effects, especially in the cardiovascular system. Blood pressure elevations are common which can be deleterious to patients with underlying hypertension or co-morbidities that react poorly to acute elevations of blood pressure such as cerebrovascular disease (stroke) or coronary artery disease (angina, myocardial infarction). Patients also often complain of a sense of inability to get their breath, to swallow, and chest tightness during the treatment.

The RespInnovation's RespIn 11 device has been demonstrated in early pilot clinical trials to have no or minimal incidence of blood pressure elevation (as compared to another currently FDA-approved device on the market. Some approved HFCWO devices are known to cause elevated BP resulting in a complication risk warning on the FDA label) and this study is designed to assess the perceived lack of BP issues with the RespIn 11 device and assess other physiologic findings and patient-reported symptoms in a rigorous standardized manner and to also demonstrate equivalent or better efficiency than existing Chest Compression devices in cough production and solicitation of secretion expectoration by patients.

ELIGIBILITY / INCLUSION / EXCLUSION CRITERIA

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INCLUSION CRITERIA

Patients males and females 18 - 89 years inclusive with pulmonary disease with significant production of pulmonary secretions (productive cough); e.g., CF, COPD (chronic bronchitis, bronchiectasis, etc.).

Patients with known elevated high blood pressure (hypertension), in addition to the underlying pulmonary disease, will be accepted. Subjects will be able to read, understand, and provide written informed consent and, in the opinion of the investigator, the subject is capable of understanding and complying with protocol requirements.

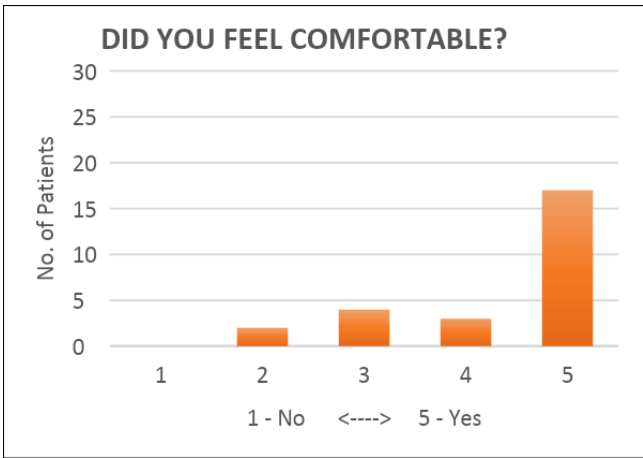
EXCLUSION CRITERIA

Any patient with a history of a myocardial infarction, pulmonary embolus, deep venous thrombosis, syncopal episode, stroke or significant traumatic injury within 12 months shall be excluded from the study;

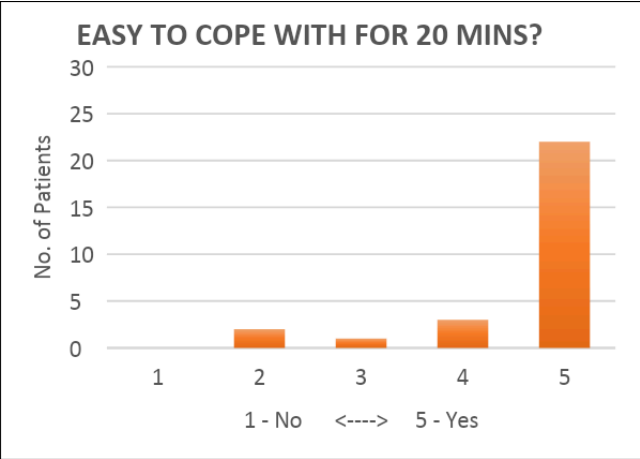
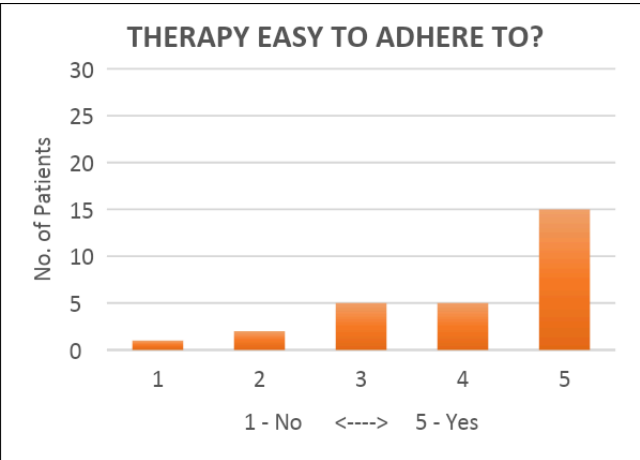
Any patient with an operation of the cranium, neck, thorax, or abdomen within 12 months shall also be excluded from the study.

GRAPHICAL RESULTS ANALYSIS

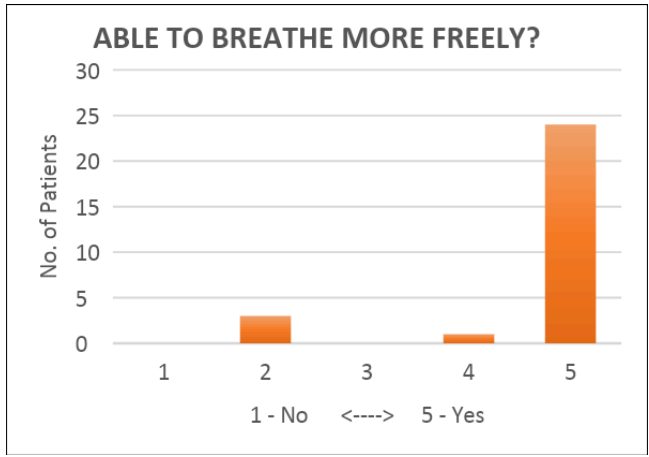
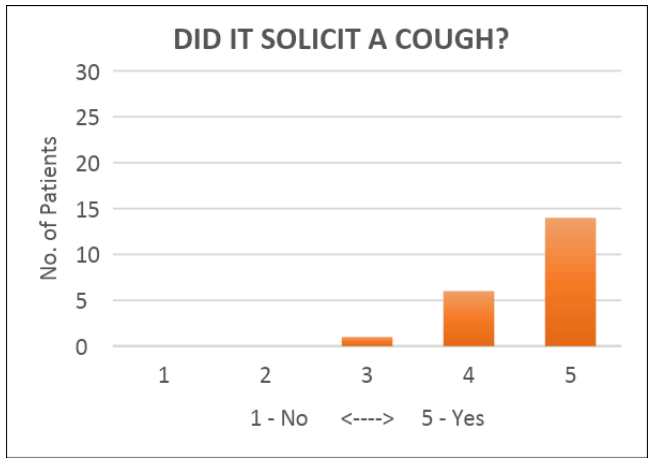
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RESULTS

Twenty Eight subjects (ages 26-89 and 14 males), are reported, 26 patients completed more than ½ the tests. One patient (3.6%) demonstrated >15% change in systolic and diastolic BP during evaluation. 13 of 28 (46.4%) patients showed an individual session decrease of > 5% in HR (only 1 > 10%) and 3 (10%) showed an individual session increase in HR > 5% (1 > 10%). Two patients (7%) of 28 showed a decrease in SpO2 of 2-4% and 10 of 28 (36%) showed an increase in SpO2 of 2 – 8%. No cardiac arrhythmias were demonstrated. Patient tolerance showed 28/28 patients (100%) found the device comfortable and easy to use. 25/28 (90%) had a cough stimulated. No patients complained of chest pain or dizziness

CONCLUSIONS

The study demonstrates the safety of the Respln 11 device with minimal changes from patients’ pre-intervention cardiopulmonary parameters except for an increase in SpO2 in 36% of the patients. There were no cardiac arrhythmias. Patient acceptance of the device was excellent and a cough was



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stimulated in 90% of patients. The new device provides a new method for mobilization of pulmonary secretions in patients.

CLINICAL IMPLICATIONS

The Respln 11 focused-pulsation chest wall device is a new method for mobilization of pulmonary secretions causing minimal, if any, change in cardiopulmonary parameters.