Protocol Director: Leigh J. Mack, MD.PhD, FAPCR, CPI

Protocol Title: Efficacy Study of Electro Flo® 5000 Airway Clearance Device.
STUDY NUMBER: 2017-7. STUDY NAME: Med Systems Electro Flo 5000 Efficacy 2017
VERSION DATE: 15 December 2018

Please check all that are applicable:

I am an adult participant between the age of 18 to 55 in this study.

Print your name here:

_____

_____

****

Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in a research study learn the level of effectiveness of the Med Systems' Electro Flo® 5000 Airway Clearance System. The device is currently already cleared by the FDA (FDA: K031876) for use by participants with cystic fibrosis to loosen and dislodge trapped bronchial secretions. You were selected as a possible participant in this study because you or your clinical provider (physician) recommended or wrote a prescription for such a device.

This research study is looking for participants with mild to severe Cystic fibrosis who live in the United States. Med Systems expects to enroll 80 research study participants.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. If you decide to terminate your participation in this study, you should notify at us by email: CFtrial@mackbio.com or Phone: 888-935-8676 ext. 706

Participant ID:

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DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 23 days from enrollment until completion. 21 days shall be the actual study period with two days before for enrollment and device setup and one days following for follow up survey.

PROCEDURES

If you choose to participate, Leigh J Mack, MD, PhD, FAPCR, CPI and his research study staff will supervise the daily use of the Electro Flo® 5000 Airway Clearance Device for helping congested locations to loosen and dislodge trapped bronchial secretions.

The study objective is to measure the efficacy of the Electro Flo® 5000. In order to get an accurate measurement, you will be asked to measure your blood oxygen level with a simple finger clip on device. This device uses light to measure the amount of oxygen in your bloodstream. The device is noninvasive and will not cause any pain and is simple to use.

Your involvement, as a participant shall involve:

1. The use of your own mobile device (Android or Apple)
2. Approximately 20 minutes per day to record information from pulse oximetry device and spirometer.
3. Answer 5 multiple choice questions, two times per week.
4. Answer an intake form and post study survey.

The Sponsor shall provide:

1. Use of free apps provided the Sponsor.
2. Use of a pulse oximeter (automatically stores information into the app)
3. Use of a spirometer.
4. Personal post study report for your medical records and healthcare provider (if you so choose)

We will ask that you follow this schedule during a 21 day period of the study:

1. Take pulse ox reading within 30 minutes of waking.
2. Use Electro Flo® 5000 as prescribed or advised by your healthcare provider to clear lungs.
3. Take pulse ox measurement again 3 hours after Electro Flo® 5000 use.
4. Use Spirometer and take picture with the app provided at 3 hours after use of the Electro Flo® 5000.

All data from the pulse oximetry device shall be recorded via the the app and automatically transferred to the study. You should only have to answer a 5 question survey two times per week. The study itself shall last 21 days. The goal of this study is to illustrate to the manufacturer (Sponsor) and CMS Medicare that the device is effective for people with cystic fibrosis for lung clearance.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Use the Electro Flo® 5000 Airway Clearance Device as directed in your prescription.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant.
- Keep the Electro Flo® 5000 Airway Clearance Device in a safe place, away from children and for your use only.
- Complete surveys.
- Complete pulse oximetry measurements.
- Use your own mobile device and free apps provided to you.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify CFtrial@mackbio.com or Phone: 888-935-8676 ext. 706

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.

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- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is canceled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are minimal risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. This study is using a device that has already been cleared by FDA and to date has zero adverse events reported to FDA.
As stated in the device manual.

CAUTION – The Electro Flo 5000 should not be used on patients who:
-Have just eaten or are vomiting
-Have acute asthma or tuberculosis
-Have brittle bones, broken ribs or severe osteoporosis
-Are bleeding from the lungs or coughing up blood
- Are experiencing intense pain
-Have increased pressure in the skull
-Have head or neck injuries
-Have collapsed lungs or a damaged chest wall
-Have recently experienced a heart attack
-Have a pulmonary embolism or lung abscess
-Have an active hemorrhage
-Have injuries to the spine
-Have open wounds or burns
-Have had recent surgery

POTENTIAL BENEFITS

- We cannot and do not guarantee or promise that you will receive any benefits from this study. The Sponsor would like to achieve a better Medicare coverage reimbursement rate for this device. Hopefully, in the future, this device shall be covered by more insurance providers and Medicare with little patient out of pocket expense.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of Electro Flo® 5000; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: CFtrial@mackbio.com or Phone: 888-935-8676 ext. 706

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, medical history, conditions before and after treatment with the medical device and your personal opinions about the medical device and your cystic fibrosis condition.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Leigh J Mack, MD, PhD, FAPCR, CPI
- The Mack Biotech, Corp. Administrative Panel on Human Subjects in Medical Research and any other unit of Mack Biotech, Corp. as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Sponsor - Med Systems, Inc.
- The Food and Drug Administration

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2019 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

Participant ID:

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FINANCIAL CONSIDERATIONS

Payment
$7.00 per study day reimbursement shall be offered for this study for each complete data submitted, for each study day, not to exceed $147.00 total for each participant.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. Because this device is already cleared by FDA; in the event that you have an injury or illness that is directly caused by your use of the device the manufacturer (Sponsor) shall be responsible as a medical device manufacturer in the State of California.

You do not waive any liability rights for personal injury by signing this form.

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

Participant ID:

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CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Leigh J. Mack, MD.PhD, FAPCR, CPI You may contact him now or later at CFtrial@mackbio.com or Phone: 888-935-8676 ext. 706

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Leigh J. Mack, MD.PhD, FAPCR, CPI CFtrial@mackbio.com or Phone: 888-935-8676 ext. 706

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Print Name of Other Parent or Guardian

_____
Authority to Act for Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

Participant ID:

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To be completed by investigator compteling intake

Person who consented this Participant _____

Date Consented:_____

Time Consented:_____

Consented on both audio and video HIPAA compliant system:_____

Signature:_____