DragONE Study: Acquisition and Maintenance of Paediatric Asthma Control: Usual Care vs Innovative Devices (DragONE)

ClinicalTrials.gov Identifier: NCT03273933

Recruitment Status : Recruiting
First Posted : September 6, 2017
Last Update Posted : January 15, 2019

See **Contacts and Locations**

Sponsor:
Istituto di Biomedicina e Immunologia Molecolare Alberto Monroy

Information provided by (Responsible Party):
Stefania La Grutta, MD, Istituto di Biomedicina e Immunologia Molecolare Alberto Monroy

Study Description

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Brief Summary:
Randomized clinical trial to assess acquisition and maintenance of paediatric asthma control through innovative devices supporting usual care. In the first study arm, a new application (DragONE) for iOS and Android will be only used for patient monitoring. In the second study arm, a small portable device (SmartONE) will also be connected to the DragONE APP, for daily assessment of the peak expiratory flow (PEF). The study duration is 12 weeks. The main outcome of the study is the Childhood Asthma Control Test (C-ACT) score, assessed once every 4 weeks for 12 weeks.

Condition or disease	Intervention/treatment	Phase
Asthma	Device: DragONE Device: SmartOne	Phase 4

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	20 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Supportive Care
Official Title:	DragONE Study: Acquisition and Maintenance of Paediatric Asthma Control: Usual Care vs Innovative Devices
Actual Study Start Date :	March 8, 2018
Estimated Primary Completion Date :	December 2019
Estimated Study Completion Date :	December 2019

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Asthma Children's Health

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: 10 children with DragONE only	Device: DragONE The DragONE application for iOS and Android, developed in collaboration with the Institute for Educational Technologies of the National Research Council of Palermo, allow children to daily fill electronically the C-ACT questionnaire and the symptom diary card.
Experimental: 10 children with DragONE and SmartOne	Device: DragONE The DragONE application for iOS and Android, developed in collaboration with the Institute for Educational Technologies of the National Research Council of Palermo, allow children to daily fill electronically the C-ACT questionnaire and the symptom diary card.

	Device: SmartOne A little portable spirometer connected to DragONE allows daily PEF monitoring.

Outcome Measures

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Primary Outcome Measures :

1. Acquisition and maintenance of the control status [Time Frame: Once every 4 weeks, for 12 weeks]

   mean C-ACT score

Secondary Outcome Measures :

1. Quality of life [Time Frame: 12 weeks]

   PAQLQ score

2. Adherence to asthma treatment [Time Frame: 12 weeks]

   MARS score

3. Lung function: FEV1 [Time Frame: 12 weeks]

   Forced expiratory volume in the first second

4. Lung function: FVC [Time Frame: 12 weeks]

   Forced vital capacity

5. Lung function: FEF 25-75 [Time Frame: 12 weeks]

   Forced expiratory flow at 25-75%

Eligibility Criteria

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Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	6 Years to 11 Years (Child)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Diagnosis of moderate persistent asthma
- Uncontrolled symptoms (C-ACT≤ 19)
- Treated for at least 3 months
- FEV1 between 60% and 90% of predicted value

Exclusion Criteria:

- Symptoms of acute respiratory infection
- Immunological or metabolic systemic disease
- Major malformations of the upper airways
- Active smoker

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03273933***

Contacts

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Locations

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Sponsors and Collaborators

Istituto di Biomedicina e Immunologia Molecolare Alberto Monroy

More Information

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ClinicalTrials.gov Identifier:	NCT03273933 History of Changes
Other Study ID Numbers:	7/2017_B
First Posted:	September 6, 2017 Key Record Dates
Last Update Posted:	January 15, 2019
Last Verified:	January 2019

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Additional relevant MeSH terms:

Asthma	Respiratory Hypersensitivity
Bronchial Diseases	Hypersensitivity, Immediate
Respiratory Tract Diseases	Hypersensitivity
Lung Diseases, Obstructive	Immune System Diseases
Lung Diseases	