Expertise Asthma COPD Program with Digital Support

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The aim of the EXACT@Home study is to further improve the assessment of treatable traits in patients with difficult to treat to severe asthma using ehealth before considering treatment with biologics.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56308

Source
ToetsingOnline

Brief title
EXACT@home

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Obstructive airway disease, symptomatic airway narrowing

Health condition

Onderste luchtwegaandoeningen: inflammatie en obstructie

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: Een extra subsidie wordt nog aangevraagd,DSW Transformatiegelden (zorgverzekeraar),TEVA Pharma,Teva Pharmaceuticals;DSW transformatiegelden

Intervention

Keyword: Care pathway, eHealth, Severe asthma, Treatable traits

Outcome measures

Primary outcome

Difference between the intervention and control group in the percentage of patients treated with biologicals after 6 months of follow up.

Secondary outcome

Percentage of patients treated with biologicals after 11-12 months of follow up, quality of life, asthma control, dyspnea perception, lung function, exacerbation frequency, prednisolone use, direct healthcare consumption, self-management skills, patient satisfaction, adherence to ICS/LABA therapy, inhaler technique, physical activity, sleep, vital parameters, breath pattern analysis with the eNose, safety of the BF-Digihaler-DS (digital inhaler) and SpiroNose (eNose) and the course of the treatment in each patient.

Study description

Background summary

Asthma is a common multifactorial disease with chronic inflammation of the lower airways. Asthma is in most cases adequately treated by inhalation medication. However, there is subgroup of patients which have uncontrolled asthma, consisting of poor symptom control and frequent asthma exacerbations. 17% of asthma patients have difficult-to-treat asthma, which is uncontrolled

despite of treatment with a medium to high dose ICS (inhaled corticosteroids) in combination with a LABA (long acting beta 2 agonists) or with maintenance OCS (oral corticosteroids). This type of asthma often appears to be difficult to treat because of the presence of treatable traits. Examples of treatable traits are poor adherence to inhalation therapy and inhaler technique, dysfunctional breathing, exposure to toxic substances and/or allergens, contraindicated medication, co-morbidities, excess weight, working conditions, reduced exercise capacity, physical inactivity and behavior.

Severe and refractory asthma is a subtype of difficult-to-treat asthma and only occurs if the asthma is uncontrolled despite optimized inhaler therapy and addressing of treatable traits. Only 3.7% of all asthma patients have this type of asthma. However, this group of patients is responsible for a high burden of overall disease, as well as large direct and indirect costs.Treatment options with biologics have fundamentally changed the care for patients with severe asthma. These drugs give a relevant improvement in asthma control, the number of asthma exacerbations and quality of life. These drugs are also very expensive and must be given for the correct indication.

The Centre of Excellence for severe Asthma, Franciscus Gasthuis & Vlietland, Rotterdam offers a weekly Multi-Disciplinary Team Meeting (MDTM) for hospitals in the South-West of the Netherlands to discuss their patients with problematic asthma. Despite maximal efforts of all stakeholders, the complete overview of a patient and thereby the presence of treatable traits is hampered by the complexity and heterogeneity of severe asthma. Franciscus Gasthuis & Vlietland offers a validated tertiary assessment to address treatable traits in detail.
To further optimize this integrated care assessment, eHealth applications with home monitoring tools will be added to the program: EXACT@home project (Expertise Asthma COPD program with digital support).

The aim of the EXACT@Home project is to create an evidence-based health program using eHealth and multiple digital devices to further improve the assessment of patients with diffcult to treat to severe and refractory asthma before starting with a treatment consisting of biologics.

We hypothesize that by using the EXACT@home, it is possible to identify and treat even more specifically the underlying *treatable traits* of asthma. This makes the treatment more targeted, prevents unnecessary or even incorrect prescription of biologics and possibly saves costs.

Study objective

The aim of the EXACT@Home study is to further improve the assessment of treatable traits in patients with difficult to treat to severe asthma using ehealth before considering treatment with biologics.

Study design

Open-label, randomized controlled trial with a superiority design.

Intervention

Patients with severe asthma who are eligible for treatment with biologics (determined at the regional asthma Multi-Disciplinary Team Meeting (MDTM)) will be included. Patients will be randomized in 2 groups (intervention - and control group). The intervention group participates in a holistic assessment called EXACT@home consisting of a period of 6 weeks addressing diagnosis, asthma phenotype and treatable traits using e.g. questionnaires and digital devices. 4 or 5 digital devices will be used:
1. A Hand-held spirometer to measuring airway obstruction: Spirobank Oxi from MIR;
2. A smart inhalation device with it's own application to monitor adherence to inhalation therapy and inhaler technique): Budesonide/Formoterol electronic multidose dry powder inhaler (BF-Digihaler) Digital System (-DS) from Teva;
3. An activity tracker with initially it's own application to measure physical activity, vital parameters and sleep): Cardiowatch 287-2 from Corsano.
4. A Fraction of Expired Nitric Oxide (FeNO) measurement device. FeNO is a surrogate marker for eosinophilic airway inflammation: Vivatmo me from Bosch. This medical device will only be used in a subgroup of patients with FeNO >45 ppb;
5. During the last week of the 6 weeks patients also receive a second activity tracker according to standard care: DynaPort MoveMonitor from McRoberts.

The information of the Spirobank Oxi, the Vivatmo me and eventually the Cardiowatch 278-2, questionnaires and all other information concerning the patient will be stored in the *Personal Digital Healthcare Environment (PDHE)* of Curavista, to which the patient and caregiver have access. The PDHE also contains an online self-management diary for the patient. The application of Corsano will initially be used for Cardiowatch 287-2 instead of the PDHE, because the connection between the Cardiowatch 287-2 and the PDHE needs to be further developed. before the PD. De BF-Digihaler from Teva has its own application in which that patient can view his/her results and the application can also give reminders/notifications on the usage of the BF-Digihaler. De data of the BF-Digihaler DS is also accessable for both the patient and the caregiver. After collecting all data, there will be an evaluation of the data extracted from the EXACT@home systematic anamnesis, questionnaires and devices. Based on this evaluation and the degree of astma control, the type of treatment will be determined: optimization of *treatable traits* or start of the treatment with biologics as previously determined at the regional asthma MDTM. The control group will immediately start a treatment with biologics after eligibility is determined at the regional asthma MDTM. In addition, the control group will also use the BF-Digihaler (but without the application, which means

these patients don't have insight into their own results and will not recieve reminders en notifications) and the PDHE. The chosen treatment of both, the intervention and control group, will be evaluated during 11-12 months of which the primary endpoint is after 6 months. During this follow up the chosen treatment can be amended or ceased. It is possible for the intervention group to eventually add a biologic during this period when a treatment of treatable traits was first chosen. In addition, both the patients in the intervention and control group will undergo an analysis of volatile compounds in the exhaled breath with an electronic nose (SpiroNose from Breathomics) at the beginning and the end of the study to measure the difference before and during treatment (biologicals).

Study burden and risks

The possible burden of the intervention group is that an effective treatment with biologics is temporarily postponed in favour of in depth assessment for a short period of 6 weeks. On the other hand the patient could benefit from the EXACT@home assessment possibly leading to a personalized treatment, in which a treatment with biologics might not be necessary anymore. Next to this, there are other possible minor burdens. For example 1 extra visit in addition to standard care. Next to this, blood samples have to be drawn during the study (standard practice) and a urine analysis (cotinine) will be performed during visit 1. Also, lung function measurements have to be performed (standard practice), which takes approximately 30-45 min each time. Furthermore, questionnaires have to be completed (from which a part is standard practice). During the first visits all questionnaires will be filled in which takes approximately 45-50 minutes for the intervention arm and 30 minutes for the control arm. During the following visits a smaller amount of questionnaires will be completed. Additionally, measurements of exhaled breath with the elektronic nose will be performed, which takes approximately 2-3 minutes each time. In addition, patients in both groups will use Curavista's Personal Digital healthcare environment (PDHE) for 11-12 months. Moreover, patients in the intervention group will have to use the Spirobank Oxi, Vivatmo me and Cardiowatch 278-2 for a period of 12 weeks. In addition, the BF-Digihaler-DS has to be used for 11-12 months in the intervention and the control group. The patient will use the Spirobank Oxi and Vivatmo me every day. The BF-Digihaler-DS substitutes the patient*s own inhaler medication. The Cardiowatch 287-2 will be worn around the wrist and the Dynaport MoveMonitor will be worn around the waist, both for 24/hours a day.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Confirmed asthma diagnosis according to the asthma guidelines.
- Diagnosed with severe, refractory asthma with eligibility for treatment with specific asthma biologics (omalizumab, mepolizumab, benralizumab, reslizumab, dupilumab, tezepelumab) as determined at the regional asthma Multi-Disciplinary Team Meeting (MDTM) according to the asthma guidelines.
- Age >= 18 years.
- Previous prescribed asthma biologics have to be ceased >= 4 times the half-life of that specific biologic.
- The patient has be relatively stable. The onset of an asthma exacerbation and/or a lower respiratory tract infection which requires a treatment with prednisolone and/or antibiotics has to be >= 2 weeks ago.

Exclusion criteria

- Primary COPD diagnosis
- History of cancer:
> Current basal cell carcinoma of the skin, localized squamous cell carcinoma

of the skin or in situ carcinoma of the cervix. Patients are eligible to participate in the study provided that curative therapy was completed at least 12 months prior to the start of the study.
> Current other malignancies. Patients are eligible to participate in the study provided that curative therapy was completed at least 5 years prior to the start of the study.
- The patient must be stable. The onset of an asthma exacerbation and/or a respiratory infection has to be >= 4 weeks ago.
- Inability to fully understand and read the Dutch language.
- Being unable to engage in a remote monitoring and coaching program through the use of a smartphone.
- Being unable to engage in physical activity (e.g. physical disability).
- Current pregnancy.
- Current breastfeeding.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2023
Enrollment:	138
Type:	Actual

Medical products/devices used

Generic name:	BF-Digihaler-DS met 4 component devices (digital inhaler;cloud;dashboard;application)

Registration:	No
Product type:	Medicine
Brand name:	Budesonide/Formoterol electronic multidose dry powder inhaler (BF-Digihaler) Digital System (DS)
Generic name:	Digitale inhaler with budesonide/formoterol

Ethics review

Approved WMO Date:	04-07-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-11-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-02-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-03-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-05-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	16-05-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-006681-21-NL
CCMO	NL79996.100.22