# An open label, randomised, parallel group clinical study to evaluate the effect of the Connected Inhaler System (CIS) on adherence to Relvar/Breo ELLIPTA therapy, in asthmatic subjects with poor control (study 207040)

Published: 13-11-2017
Last updated: 12-04-2024

Primary:To compare the effect of 6 months use of the CIS on adherence to ELLIPTA maintenance therapy when both the subject and the HCP are supplied with data from the maintenance sensor versus no data supplied to the subject and HCP (Arm 1 vs Arm 5...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bronchial disorders (excl neoplasms) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON46712

**Source**
ToetsingOnline

**Brief title**
study 207040

### Condition

- Bronchial disorders (excl neoplasms)

**Synonym**
bronchial asthma; asthma

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** GlaxoSmithKline
**Source(s) of monetary or material Support:** GlaxoSmithKline BV

## Intervention

**Keyword:** adherance, asthma, CIS, Relvar ELLIPTA

## Outcome measures

### Primary outcome

Percentage of ELLIPTA doses between the beginning of month 4 and the end of month 6 as determined by the maintenance sensor.

### Secondary outcome

Percentage of ELLIPTA doses between the beginning of month 4 and the end of month 6, beginning of month 1 and the end of month 3 and beginning of month 1 and the end of month 6 as determined by the maintenance sensor. Percentage of rescue free days and total rescue use measured between the beginning of month 4 and the end of month 6 as determined by the rescue sensor records of date, time, and number of inhaler actuations. Change from baseline in ACT total score at Month 6, measured at baseline and Month 6. Percentage of patients becoming controlled as defined as an ACT score *20 at Month 6. Percentage of patients with an increase from baseline * 3 in ACT total score at Month 6. Adverse events.

# Study description

### Background summary

GSK has, in collaboration with Propeller Health, developed a sensor which clips on to the ELLIPTA dry powder inhaler (DPI), herein referred to as ELLIPTA. The sensor will measure when the ELLIPTA mouth piece cover is fully opened and closed and this data can be fed back, via an application (app) on a smart phone to the patient. This will inform a patient if/when a dose of Relvar has been actuated from the ELLIPTA. Other information, including: asthma management strategies, tracking of symptoms, asthma triggers and medication reminders, will also be provided via the app. Information from a second sensor on a patient*s rescue medication metered dose inhaler (MDI) could also provide feedback, via the app, to the patient on their salbutamol (albuterol) MDI use. The data from both Relvar ELLIPTA and salbutamol MDI can also be shared, via an online dashboard, with the patient*s investigator. The sensors, app, dashboard and systems to provide data are subsequently described as the Connected Inhaler System (CIS).
This study will be the first to evaluate the effect of the CIS on adherence to maintenance therapy (Relvar ELLIPTA) in uncontrolled asthmatic patients (Asthma Control Test [ACT] <20 at the screening visit and ACT <20 at a subsequent randomization visit after run-in). The run-in exists to ensure a stable level of control prior to entry into the study, given the possible change in treatment.
Relvar ELLIPTA has been registered in the Netherlands for the treatment of e.g. bronchial asthma. It is a combination of a dry powder formulation of a corticosteroid and a long acting bronchodilator in a once daily schedule.

## Study objective

Primary:
To compare the effect of 6 months use of the CIS on adherence to ELLIPTA maintenance therapy when both the subject and the HCP are supplied with data from the maintenance sensor versus no data supplied to the subject and HCP (Arm 1 vs Arm 5)
Secondary:
To compare the effect of 6 months use of the CIS on adherence to ELLIPTA maintenance therapy for the following aspects of the CIS: Arm 2 vs Arm 5, Arm 3 vs Arm 5, Arm 4 vs Arm 5. To compare the effect of the CIS on adherence to ELLIPTA maintenance therapy of the individual CIS treatment arms versus no data supplied to the subject and HCP. To evaluate the effect of 6 months use of the CIS on a subject*s rescue medicine usage and asthma control. Safety.

## Study design

Open-label, randomised, parallel group study consisting of 5 treatment arms.
1 month run-in on Relvar ELLIPTA (up to 3 months if needed) to confirm lack of asthma controle (Asthma Control Test (ACT)) <20).
Randomization (1:1:1:1:1) to the following Arms for 6 months:
1. Data on Maintanance use supplied to Subject (app) and investigator

(dashboard).
2. Data on Maintanance use supplied to Subject (app).
3. Data on Maintanance use and Rescue use supplied to Subject (app) and investigator (dashboard).
4. Data on Maintanance use and Rescue use supplied to Subject (app).
5. No data supplied to Subject or investigator.
All randomized subjects will be treated with Relvar ELLIPTA.
432 subjects (600 to be screened), see also sample size re-estimation in section 5.2 of the protocol.

**Intervention**

Treatment with Relvar ELLIPTA. Different levels of information supply on maintenance and rescue use.

**Study burden and risks**

Risk: Adverse events of Relvar ELLIPTA.
Burden:
5-11 visits in 7-9 months.
Complete physical examination: once.
Pregnancy test: 4-6 times (urine).
FeNO test 4-6 times.
Peak flow: 4-6 times.
Questionnaires: 6 (3-4 times), 1 (once).

# Contacts

**Public**
GlaxoSmithKline

Huis ter Heideweg 62
Zeist 3705 LZ
NL
**Scientific**
GlaxoSmithKline

Huis ter Heideweg 62
Zeist 3705 LZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

* Males and females at least 18 years of age.
* Documented diagnosis of asthma.
* Asthma Control Test <20 at screening.
* Asthma Control Test (ACT) score <20 at randomization.
* Non-smokers (never smoked or not smoking for >6 months with <10 pack years history).
* Subject must have been on maintenance therapy (Fixed dose combination ICS/LABA) for 3 months. See protocol page 31 for details).
* Background asthma medication such as anti-leukotrienes and oral corticosteroids are permitted provided the dose has been stable for 1 month prior to screening.
* Female participants of childbearing potential should agree to follow the contraceptive guidance in appendix 5 of the protocol during the treatment period and for at least 5 days after the last dose of study treatment.

## Exclusion criteria

* History of life-threatening asthma. See protocol page 32 for details.
* Lower airway infection in the last 7 days before screening.
* COPD or other respiratory disorders. See protocol page 32 for details.
* Other diseases: See protocol page 32 for details.
* Ever received treatment with biological based therapy.
* Pregnancy or lactation.

# Study design

## Design

| | |
|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 13-03-2018 |
| Enrollment: | 31 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Generic name: | Connected Inhaler System (CIS) |
| Registration: | Yes - CE intended use |
| Product type: | Medicine |
| Brand name: | Relvar ELLIPTA |
| Generic name: | Fluticasone Furoate en Vilanterol |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Ventolin |
| Generic name: | Salbutamol |
| Registration: | Yes - NL intended use |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 13-11-2017 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United |

| | |
|---|---|
| | (Nieuwegein) |
| Approved WMO Date: | 08-02-2018 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 21-02-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 28-02-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 17-04-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 25-04-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 24-09-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 25-09-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 18-10-2018 |

| | |
|---|---|
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 24-10-2018 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 12-02-2019 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 04-03-2019 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 05-06-2019 |
| 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 | EUCTR2017-002266-45-NL |
| CCMO | NL63491.100.17 |
| Other | www.gskclinicalstudyregister.com 207040 |