Study ID

Sponsor protocol code CHIT-2101
ClinicalTrials.gov NCT05168995

Study Title

Effects of beclometasone dipropionate/formoterol fumarate fixed combination administered with the NEXT(haler) in a rEal-World study on The probability Of improving the asthma coNtrol status after 6 months of treatment. The NEWTON study

Rationale

Despite the positive results in the treatment of asthma reported in the literature, a relevant gap still exists between the results of clinical trials, in which many patients achieve asthma control through pharmacological treatment and the epidemiological data, which suggest that many patients with asthma treated as per standard clinical practice still have poorly controlled disease. Thus, real-life studies are needed to better understand asthma treatment in larger and more diverse patient populations and identify what factors in the real-life context are associated with poor asthma control.

Study Phase

Observational

Study Period

FPFV: 12 April 2022

LPLV: 09 February 2024

Study Design

Multicentre, cohort, prospective, longitudinal observational study

Inclusion and Exclusion criteria

Inclusion criteria:

1. Male or female patients aged ≥18 years;
2. Patients enrolled on the same day as the first prescription with BDP/FF NEXThaler® 100/6 micrograms, or having ongoing treatment with BDP/FF NEXThaler® 100/6 micrograms started within the previous 14 days (maximum), as per local standard clinical practice. In both cases, physician's decision of prescribing BDP/FF NEXThaler® 100/6 micrograms has been taken before the patient inclusion in the study and is completely independent from the study protocol;
3. Not adequately controlled asthmatic patients (according to clinician's judgement) when BDP/FF NEXThaler® 100/6 micrograms was prescribed;
4. Patients not treated with extrafine formulations during the 6 months before starting the treatment with BDP/FF NEXThaler®;
5. Written informed consent to participate in the study and for the processing of personal data.

Exclusion criteria:

1. Recent (i.e. within the last 6 months) history of life-threatening asthma exacerbations;
2. Diagnosis of chronic obstructive pulmonary disease (COPD);
3. Asthmatic patients on treatment with biologic agents (e.g. monoclonal antibodies) and/or extemporary or fixed triple combinations (e.g. long-acting β2 agonist (LABA)/long-acting muscarinic antagonist (LAMA)/inhaled corticosteroid (ICS) at any dose regimen;
4. Patients with uncontrolled/clinically significant diseases (according to clinician's judgement) or inability to understand and fill in study questionnaires;
5. Concomitant participation in experimental clinical studies/investigations or participation in experimental clinical studies/investigations within 3 months prior to enrolment into the present study.

Center(s)

52 centres distributed among six countries as follows:

France: 8 centres;
Germany: 9 centres;
Hungary: 5 centres;
Italy: 19 centres;
Romania: 5 centres;

Spain: 6 centres

Indication(s)

Asthma

Treatment(s)

BDP/FF NEXThaler® 100/6 micrograms per actuation inhalation powder (equivalent to a delivered dose [the dose leaving the mouthpiece] of 81.9 micrograms of beclometasone dipropionate anhydrous and 5.0 micrograms of formoterol fumarate dihydrate).

Study Objectives

Primary objective:
The primary objective of the study was to assess the probability of improving the asthma control status over a 6-month time period using the 5-item version of the Asthma Control Questionnaire (ACQ-5), following treatment with BDP/FF NEXThaler® 100/6 µg.
Key Secondary objectives:

- To describe the effects of BDP/FF NEXThaler® 100/6 µg on:
- Change at 6 months from baseline in quality of life (QoL) and adherence;
- Adherence to the most recent previous inhaled asthma treatment;
- Incidence of asthma exacerbations over 6 months.
- To describe the safety of BDP/FF NEXThaler® 100/6 µg over 6 months.

Endpoints/Variables

Primary variables:
• Proportion of patients improving the level of asthma control (based on ACQ-5 score) at V3 (from poorly controlled to not well-controlled nor poorly controlled, from poorly controlled to well controlled, from not well-controlled nor poorly controlled to well controlled).
Secondary variables:
• Proportion of patients achieving minimal clinically important improvement in ACQ-5 scores, as defined by ACQ-5 score decrease of at least 0.5 points at V3;
• Change from baseline in QoL using EuroQol 5-dimension 5-level version (EQ-5D-5L);
• Adherence to treatment with BDP/FF NEXThaler® using TAI-12;
• Occurrence of moderate-to-severe exacerbations during the overall observation period;
• Safety variables.

Statistical Methods

The study had a descriptive aim: results of statistical analyses from the study data were presented in form of descriptive statistics.
Continuous variables were summarized by number of observations, mean, standard deviation (SD), median, quartiles, minimum, and maximum. Categorical variables were summarized using counts of patients and percentages.

Study Population/Demographic

Characteristics	Evaluable subjects (N=423)
Gender (n, %)	
Male	136 (32.2%)
Female	287 (67.8%)
Age, years	
Median (IQR)	49.0 (34.0-61.0)
Mean (SD)	48.1 (17.2)
Age classes, n (%)	
18-34 years old	107 (25.3%)
35-59 years old	194 (45.9%)
>=60 years old	122 (28.8%)
Smoking status, n (%)	

Non-smoker	275 (65.0%)
Current smoker	67 (15.8%)
Ex-smoker	81 (19.1%)
Body Mass Index (BMI) classes, n (%)	N=411
Underweight	7 (1.7%)
Normal weight	150 (36.5%)
Overweight	131 (31.9%)
Obese	123 (29.9%)

Efficacy/Effectiveness Results

	EVALUABLE PATIENTS with ACQ-5 questionnaire at baseline and 6-month follow-up N=395			
ACQ-5 score	Baseline	6-month follow-up	Change 6-month f-up vs Baseline	p-value
N	395	395	395	<0.0001
Mean	2.0	0.8	-1.3	
SD	1.1	0.8	1.2	
25th percentile	1.2	0.0	-2.2	
Median	2.0	0.6	-1.2	
75th percentile	3.0	1.2	-0.4	
Min	0.0	0.0	-4.4	
Max	4.6	3.6	2.2	

	EVALUABLE PATIENTS with ACQ-5 questionnaire at baseline and at 6-month follow-up N=395	
	N (%)	95% CI
Patients improving the level of asthma control from baseline to 6-month follow-up	261 (66.1%)	61.2 - 70.7
Patients achieving minimal clinically important improvement in ACQ-5 score at 6-month follow-up respect to baseline	279 (70.6%)	65.9 - 75.1

	EVALUABLE PATIENTS with available EQ-5D-5L at baseline and 6-month follow-up N=391		
EQ-5D INDEX	Baseline	6-month follow-up	p-value
N	391	391	<0.0001
Mean	0.859	0.942	
SD	0.159	0.094	
25th percentile	0.801	0.913	
Median	0.887	1.000	
75th percentile	0.970	1.000	
Min	-0.085	0.287	
Max	1.000	1.000	

	EVALUABLE PATIENTS with available TAI enrolment and 6-month follow-up N=345		
TAI score	Baseline	6-month follow-up	p-value
N	345	345	<0.0001
Mean	44.3	46.6	
SD	6.3	5.4	
25th percentile	41.0	45.0	
Median	46.0	49.0	
75th percentile	50.0	50.0	
Min	10.0	10.0	

Max	50.0	50.0

Level of adherence	Baseline	6-month follow-up
Good (score=50)	105 (30.4%)	172 (49.9%)
Intermediate (score = 46–49)	76 (22.0%)	77 (22.3%)
Poor (score ≤45)	164 (47.5%)	96 (27.8%)

The 10-item TAI score range from 10 ('poor adherence') to 50 ('good adherence').

Safety Results

	SAF PATIENTS (N=609)
Patients experiencing moderate-severe exacerbations during observation period	21 (3.4%)
-experiencing 1 moderate-severe exacerbation	20 (3.3%)
-experiencing >1 moderate-severe exacerbation	1 (0.2%)

	SAF PATIENTS (N=609)
Patients with at least one Treatment-Emergent Adverse Event (TEAE)	62 (10.2%)
Patients with at least one TEAE related to BDP/FF NEXThaler	26 (4.3%)
Patients with at least one Serious TEAE	3 (0.5%)
Patients with at least one Serious TEAE related to BDP/FF NEXThaler	0 (0.0%)
Patients with at least one TEAE leading to treatment discontinuation	13 (2.1%)
Patients with at least one TEAE leading to death	1 (0.2%)
Patients with at least one TEAE related to BDP/FF NEXThaler leading to death	0 (0.0%)

Conclusion

The NEWTON study showed an improvement in asthma control among non-adequately controlled asthmatic patients treated in routine clinical practice with BDP/FF NEXThaler® 100/6 µg. The improvement in asthma control was accompanied by an improvement in quality of life and adherence to the treatment. The study also confirmed the good tolerability profile of the drug in real practice. This study, conducted in Europe in real-world setting, confirms that treatment with BDP/FF NEXThaler® 100/6 µg improves control of asthma with a rapid action and positively impacts patients' everyday life.

Publication(s)

J Asthma Allergy. 2023 Oct 25;16:1177-1186.
Respir Med. 2025 Oct:247:108224.

Updated on

14/11/2025