Sponsor: Techorizon

Study: Pilot Study - PILOT

Print:

- Blank CRF

V0 - Pre Screening

CRF1

Visit date

Visit date _____

Demographics

Date of birth _____

Age? _____

Sex
- ○ Male
- ○ Female

Race
- ○ Asian
- ○ Black
- ○ Caucasian
- ○ Other, specify: _____

CRF2

ICF

Written signed and dated informed consent obtained
- ○ Yes
- ○ No

Prescreening Number

Insert Prescreening Number of patient _____

Asthma

Clinical diagnosis of asthma for >= 6 months
- ○ Yes
- ○ No

Inclusion

○ Yes
○ No

the patient using inhaled corticosteroids (ICS) in monotherapy or using ICS in a fixed or free combination with long acting beta2 agonists (LABA) at a constat dose (changes in doses for less than seven days are accepted) for two months before V1.
In case patients are under ICS only,the daily dose must be >= non-extrafine 1000 ug BDP or equivalent.
In case patients are under ICS+LABA,the ICS daily dose must be >= non-extrafine 500 ug BDP or equivalent. LABA should have been stopped at least 24h before V1.
Equivalence to:
BDP non-extrafine(NE) >=500 ug BDP >=1000 ug BDP (NE):
BDP extrafine >=200 ug >=400 ug
Budesonide >=400 ug >=800 ug
Ciclesonide >=160 ug >=320 ug
Flunisolide >=1000 ug >=2000 ug
Fluticasone >=250 ug >=500 ug
Mometasone >=400 ug >=800 ug
Triamcinolone >=1000 ug >=2000 ug (yes/no)

Study treatment dispensation

Maintenance medication delivery
○ Yes
○ No

Maintenance kit number _____

rescue medication delivery
○ Yes
○ No

Rescue kit number _____

CRF3

Smoking habits

Smoker?
○ Non - Smoker
○ Current Smoker
○ Ex-Smoker

For ex-smokers only: period _____

For ex-smokers only: numbers of pack-years _____

Calculation: Pack-years= ((no.of cigarettes smoked per day)*(no.years of smoking))/20

CRF4

Vital sign, weight, height

Weight _____

BMI _____

Height _____

Heart Rate _____

Blood pressure (systolic) _____

Blood pressure (diastolic) _____

Physical examination

1.Cardiovascular System
2.Sensorial System
3.Reproductive System
4.Immune System
5.Respiratory System
6.Gastrointestinal System
7.Musculoskeletal System
8.Skin and Appendages
9.Nervous System
10.Renal and Urinary System
11.Endocrine and Metabolism Systems
12.Others

Was the assessment performed?
- ○ Yes
- ○ No

Pregnancy test

Pregnancy test
- ○ POS
- ○ NEG

CRF5

Medical/surgical history and concomitant diseases

Please record below any relevant medical/surgical condition(s) including ASTHMA. In case of clinically significant abnormalities please verify that the Inclusion/Exclusion criteria are not violated --> In case they are violated,the patient cannot be enrolled. Please fill in the "Study Termination" form. Disease, Abnormality, Condition, or Allergy

There are present any medical/surgical history or concomitant diseases?
- ◉ Yes

No

Medical/surgical history and concomitant diseases

tabella

CRF6

Spirometry

Date of Spirometry: _____

FVC actual value _____

FEV1 predicted normal value * _____

FEV1 actual value _____

FEV1% of predicted normal value ** _____

FEF 25-75% actual value _____

*automatically calculated by the system according to Quanjer et al. **automatically calculated by the system.

CRF7

Laboratory data

Date of blood sample collection _____

Plasma Glucose _____

Serum Potassium _____

Is there any parameter in the Haematology/Biochemistry results that is considered as Clinically Significant Abnormal?

- ○ Yes
- ◉ No

If "YES" and the clinically significant abnormality is due to a pre-existing condition, fill in the "Medical/Surgical History and Concomitant Diseases" form.
If "YES" and it is a new safety finding record in the "Adverse Event" form

Blood exam

tabella

CRF8

Disease

CRF9

End of visit

Does the patient continue in the study?
○ Yes
○ No

V1 - Screening

CRF1

Visit date

Visit date _____

Vital sign, weight, height

Heart Rate _____

Blood pressure (systolic) _____

Blood pressure (diastolic) _____

CRF2

Physical examination

1.Cardiovascular System
2.Sensorial System
3.Reproductive System
4.Immune System
5.Respiratory System
6.Gastrointestinal System
7.Musculoskeletal System
8.Skin and Appendages
9.Nervous System
10.Renal and Urinary System
11.Endocrine and Metabolism Systems
12.Others

Was the assessment performed? ○ Yes ○ No

Medical/surgical history and concomitant diseases

Please record below any relevant medical/surgical condition(s) including ASTHMA. In case of clinically significant abnormalities please verify that the Inclusion/Exclusion criteria are not violated --> In case they are violated,the patient cannot be enrolled. Please fill in the "Study Termination" form. Disease, Abnormality, Condition, or Allergy

There are present any medical/surgical history or concomitant diseases? ○ Yes

No

Medical/surgical history and concomitant diseases

tabella

Previous and concomitant medications

Any concomitant medication?
- ○ Yes
- ○ No

Previous and concomitant medications

tabella

CRF3

Laboratory data

Date of blood sample collection _____

Plasma Glucose _____

Serum Potassium _____

Is there any parameter in the Haematology/Biochemistry results that is considered as Clinically Significant Abnormal?
- ○ Yes
- ○ No

If "YES" and the clinically significant abnormality is due to a pre-existing condition, fill in the "Medical/Surgical History and Concomitant Diseases" form.
If "YES" and it is a new safety finding record in the "Adverse Event" form

Blood exam

tabella

Pregnancy test

Pregnancy test
- ○ POS
- ○ NEG

End of visit

Are there any AEs? If Yes please fill in adverse event log	○	Yes
	○	No
Are there any SAEs? If Yes please fill in adverse event log, the patient should be dropped	○	Yes
	○	No
Does the patient continue in the study?	○	Yes
	○	No

V2 - Randomization

CRF1

Visit date

Visit date _____

Vital sign, weight, height

Heart Rate _____

Blood pressure (systolic) _____

Blood pressure (diastolic) _____

Randomization

Is the patient eligible for randomization?
- ○ Yes
- ○ No

Spirotel

SpirotelTM delivery
- ○ Yes
- ○ No

Spirotel Serial Number _____

CRF2

Physical examination

1.Cardiovascular System
2.Sensorial System
3.Reproductive System
4.Immune System
5.Respiratory System
6.Gastrointestinal System
7.Musculoskeletal System
8.Skin and Appendages
9.Nervous System
10.Renal and Urinary System
11.Endocrine and Metabolism Systems
12.Others

Was the assessment performed?
○ Yes
○ No

Medical/surgical history and concomitant diseases

Please record below any relevant medical/surgical condition(s) including ASTHMA. In case of clinically significant abnormalities please verify that the Inclusion/Exclusion criteria are not violated --> In case they are violated,the patient cannot be enrolled. Please fill in the "Study Termination" form. Disease, Abnormality, Condition, or Allergy

There are present any medical/surgical history or concomitant diseases?
○ Yes
○ No

Medical/surgical history and concomitant diseases

tabella

Spirometry

Date of Spirometry: _____

FVC actual value _____

FEV1 predicted normal value * _____

FEV1 actual value _____

FEV1% of predicted normal value ** _____

FEF 25-75% actual value _____

*automatically calculated by the system according to Quanjer et al. **automatically calculated by the system.

Previous and concomitant medications

Any concomitant medication?
○ Yes
○ No

Previous and concomitant medications

tabella

CRF3

Laboratory data

Date of blood sample collection _____

Plasma Glucose _____

Serum Potassium _____

Is there any parameter in the Haematology/Biochemistry results that is considered as Clinically Significant Abnormal?
- ○ Yes
- ○ No

If "YES" and the clinically significant abnormality is due to a pre-existing condition, fill in the "Medical/Surgical History and Concomitant Diseases" form.
If "YES" and it is a new safety finding record in the "Adverse Event" form

Blood exam

tabella

Pregnancy test

Pregnancy test
- ○ POS
- ○ NEG

End of visit

Are there any AEs? If Yes please fill in adverse event log
- ○ Yes
- ○ No

Are there any SAEs? If Yes please fill in adverse event log, the patient should be dropped
- ○ Yes
- ○ No

Does the patient continue in the study?
- ○ Yes
- ○ No

V3 - End of treatment

CRF1

Visit date

Visit date _____

Vital sign, weight, height

Heart Rate _____

Blood pressure (systolic) _____

Blood pressure (diastolic) _____

CRF2

Vital sign, weight, height

Heart Rate _____

Blood pressure (systolic) _____

Blood pressure (diastolic) _____

Physical examination

1.Cardiovascular System
2.Sensorial System
3.Reproductive System
4.Immune System
5.Respiratory System
6.Gastrointestinal System
7.Musculoskeletal System
8.Skin and Appendages
9.Nervous System
10.Renal and Urinary System
11.Endocrine and Metabolism Systems
12.Others

Was the assessment performed?
- ○ Yes
- ○ No

Medical/surgical history and concomitant diseases

Please record below any relevant medical/surgical condition(s) including ASTHMA. In case of clinically significant abnormalities please verify that the Inclusion/Exclusion criteria are not violated --> In case they are violated,the patient cannot be enrolled. Please fill in the "Study Termination" form. Disease, Abnormality, Condition, or Allergy

There are present any medical/surgical history or concomitant diseases?
○ Yes
○ No

Medical/surgical history and concomitant diseases

tabella

Spirometry

Date of Spirometry: _____

FVC actual value _____

FEV1 predicted normal value * _____

FEV1 actual value _____

FEV1% of predicted normal value ** _____

FEF 25-75% actual value _____

*automatically calculated by the system according to Quanjer et al. **automatically calculated by the system.

Previous and concomitant medications

Any concomitant medication?
○ Yes
○ No

Previous and concomitant medications

tabella

CRF3

Laboratory data

Date of blood sample collection _____

Plasma Glucose _____

Serum Potassium _____

Is there any parameter in the Haematology/Biochemistry results that is considered as Clinically Significant Abnormal?
○ Yes
○ No

If "YES" and the clinically significant abnormality is due to a pre-existing condition, fill in the "Medical/Surgical History and Concomitant Diseases" form.
If "YES" and it is a new safety finding record in the "Adverse Event" form

Blood exam

tabella

Pregnancy test

Pregnancy test
○ POS
○ NEG

Adverse event

Are there any AEs? If Yes please fill in adverse event log
○ Yes
○ No

Are there any SAEs? If Yes please fill in adverse event log, the patient should be dropped
○ Yes
○ No

CRF4

Study termination

Completed
○ Yes
○ No

Discontinued due to Adverse Event
○ Yes
○ No

Discontinued due to lack of efficacy
○ Yes
○ No

Site Number: _____
Patient Id: ___

Discontinued due to lost to follow-up
- ○ Yes
- ○ No

Development of study specific/specify discontinuation criteria
- ○ Yes
- ○ No

Discontinued due to non compliance with study drug
- ○ Yes
- ○ No

Discontinued due to Death
- ○ Yes
- ○ No

Discontinued due to withdrawal of consent
- ○ Yes
- ○ No

Discontinued due to Other/specify
- ○ Yes: specify _____
- ○ No

Date of completion/discontinuation _____

Date of lastintake of study treatment _____

Total of Spirometry _____

Treatment unblinded
- ○ Yes
- ○ No

Date when the treatment was unblinded _____

Reason for unblinding _____

Adverse Event

CRF1

Adverse event

Any adverse event?

- ○ Yes
- ○ No

Events

tabella