Multi-centre, randomized, double-blind, parallel-group study evaluating the effect of Fluticasone Furoate/ Vilanterol (FF/VI) Inhalation Powder once daily compared with Vilanterol (VI) Inhalation Powder Once Daily on Bone Mineral Density (BMD) in subjects with Chronic Obstructive Pulmonary Disease (COPD) (HZC102972)

Published: 07-11-2013
Last updated: 23-04-2024

Effect on bone mineral density.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON44651

Source
ToetsingOnline

Brief title
HZC102972

Condition

- Bone disorders (excl congenital and fractures)
- Respiratory disorders NEC

Synonym
COPD; chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: BMD, COPD, Corticosteroids, Inhaled

Outcome measures

Primary outcome

Bone mineral density hip.

Secondary outcome

Bone mineral density lumbar spine. Adverse events.

Study description

Background summary

Although inhaled corticosteroids have demonstrated utility in patients with COPD, there is a potential safety concern with long-term use of ICS on bone demineralization. These concerns, for the most part, are derived from the well-documented effects of oral corticosteroids on bone density and fracture; however the actual effects of inhaled corticosteroids are not clear and require further study.
Study HZC102972 will prospectively assess the effects of 3 years (156 weeks) exposure to Fluticasone Furoate /Vilanterol (FF/VI) Inhalation Powder versus VI on bone mineral density in adult subjects with COPD.
Fluticasone is an inhaled corticosteroid and vilanterol is a long acting ß2-agonist. The combination has recently been registered in the EU.

Study objective

Effect on bone mineral density.

Study design

Multicenter randomized double blind phase IV parallel group study. Single-blind run-in period of 2-3 weeks.
Randomisation (1:1) to treatment with:
* Fluticasone Furoate /Vilanterol (100/25 mcg) once daily
* Vilanterol (25 mcg) once daily
administration as inhaled dry powder formulation.
Treatment duration approx 3 years.
Approx 280 randomized patients.

Intervention

Treatment with fluticasone furoate/vilanterol or vilanterol.

Study burden and risks

Risk: Adverse effects of study medication.
Burden:
Visits: screening, 1st treatment day, thereafter every 3 months during approx. 3 years. Final telephone consultation. Duration 1-3 hours.
Physical examination: screening, therafter yearly.
Inspection mouth and throat: every visit.
Blood draw 20 ml, ECG, chest X-ray and (if relevant) pregnancy test at screening.
Pulmonary function test at screening (incl. reversibility) and every 6 months thereafter.
DEXA scan: screening, thereafter every 6 months.
Daily completion of diary (medication use, concomitant medical problems, concomitant medication).
Optional pharmacogenetic research (saliva).

Contacts

Public
GlaxoSmithKline BV

Huis ter Heideweg 62
Zeist 3705 LZ
NL
Scientific
GlaxoSmithKline BV

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

* COPD patients *40 years of age (see protocol page 16 for details).
* (Ex) smokers, at least 10 pack years.
* Pre and post salbutamol FEV1/FVC ratio <70%.
* Post salbutamol FEV1 *50% and *70% of predicted.
* At least one native hip..
* Safe contraception for women of childbearing potential.

Exclusion criteria

* Pregnancy, lactation.
* Bronchial asthma.
* Poorly controlled COPD (see protocol page 17 for details).
* Bone disorders (see protocol page 17 for details).
* Immobility.
* Low vitamin D (see protocol page 18 for details)
* Use of prohibited medication (see protocol page 19 for details).

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2014
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Relvar Ellipta
Generic name:	fluticasone furoate / vilanterol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	vilanterol
Generic name:	vilanterol

Ethics review

Approved WMO Date:	07-11-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-01-2014

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-01-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-04-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-06-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-06-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	26-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-01-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-01-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-03-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-12-2016
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-12-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-04-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-10-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-01-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-04-2018
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
Other	clinicaltrials.gov; NCT01957150
EudraCT	EUCTR2012-004801-28-NL
CCMO	NL46657.060.13