PGx7612: Pharmacogenetic investigation of the association of the ADRB2 rare variant, Thr164Ile with severe asthma exacerbation (204661)

First published: 04/08/2015

Last updated: 18/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS10464

Study ID

42099

DARWIN EU® study

No

Study countries

United States

Study description

A recent publication (Lancet Respiratory Medicine 2014, 2:204-213) described evidence of association between a genetic variant, Thr164Ile, in the ADRB2 gene with hospitalization due to asthma exacerbations in non-Hispanic white patients treated with long-acting beta agonists (LABAs). Insufficient numbers of hospitalization events are documented among LABA-treated patients in GSK clinical studies to attempt a direct replication of this paper's findings. However, to better understand risk / benefit for our LABA-treatment regimes, we plan to explore the effect of this genetic variant (ADRB2 Thr164Ile) on the related endpoint evaluated in GSK clinical studies, clinically significant asthma exacerbations. The sample for this study will comprise genetic samples with relevant clinical data from patients enrolled in the studies HZA106837, ADA109055, and ADA109057.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/05/2015

Actual: 04/05/2015

Study start date

Planned: 29/05/2015

Actual: 13/07/2015

Data analysis start date

Planned: 29/05/2015

Actual: 13/07/2015

Date of final study report

Planned: 17/03/2016

Actual: 22/02/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-204661-reporting-and-analysis-plan-redact.pdf (368.63 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Pharmacogenetic study

Data collection methods:

Secondary use of data

Main study objective:

Determine if there is evidence for the association of ADRB2 Thr164Ile with clinically significant asthma exacerbation in non-Hispanic white subjects treated with LABA.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, non-interventional exploratory genetic investigation study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

FLUTICASONE FUROATE

VILANTEROL TRIFENATATE

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Non-Hispanic white (NHW) subjects from HUI 06837 , ADA109055, and ADAI 09057 who were actually treated with Fluticasone Furoate/Vilanterol (GW685698 GW642444) in HZAI 06837 or Fluticasone Propionate/Salmeterol (GR33343+CC118781) in ADA109055 and ADA109057 and for whom the requisite genetic and clinical data were available.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

876

Study design details

Outcomes

Clinically significant asthma exacerbations are defined as the requirement of treatment with an oral or parenteral corticosteroid or an unscheduled urgent care visit (e.g. unscheduled clinic visit, physician office visit, ED visit, hospitalization) for acute asthma symptoms requiring intervention.

Data analysis plan

Retrospective analyses to test for an effect of the ADRB2 Thr164Ile genotype on asthma exacerbation rate in subjects treated with LABA-containing products.

Documents

Study results

gsk-204661-clinical-study-result-summary.pdf (247.7 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

HZA106837, ADA109055, and ADA109057 clinical trials

Data sources (types)

Other

Data sources (types), other

Clinical Trial Data

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No