PRJ2282/201491: CHESS: CPRD-COPD Hawthorne Effect Study in Salford: A UK cohort study to characterise patients enrolled in the Salford Lung Study and to evaluate a potential Hawthorne effect

First published: 06/11/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10376

Study ID

48244

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The Salford Lung Study (SLS) is a unique Phase IIIB pragmatic trial evaluating the effectiveness of a novel medicine – RELVAR – compared with standard of care (SOC) among patients with Chronic Obstructive Pulmonary Disease (COPD). The trial is taking place in Salford, England. While the pragmatic nature of the trial is designed to test effectiveness in routine care, there are at least two possible concerns: 1) Salford may not be representative of the wider population in which the medicine may be used, and 2) there may be differences in local practice or changes to local practice caused by the study (the Hawthorne effect), which may artificially inflate the benefits of both RELVAR and SOC. The aim of this study (CHESS) is to evaluate the representativeness of Salford, and the potential Hawthorne effect to place the SLS in wider context.

Study status

Finalised

Research institutions and networks

Institutions

Centre for Health Informatics (CHI), University of Manchester

United Kingdom

First published: 15/07/2015

Last updated: 20/08/2024

Institution **Educational Institution**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sperrin Matthew

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/03/2015

Study start date

Planned: 02/04/2012

Actual: 23/10/2015

Data analysis start date

Planned: 04/01/2016

Date of interim report, if expected

Planned: 10/05/2016

Date of final study report

Planned: 30/12/2016

Actual: 27/08/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

CHESS_Proposal_PRJ2282_FINAL.pdf (909.57 KB)

gsk-201491-protocol-redact-v02.pdf (9.9 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

Characterize the patients enrolled in the Standard of Care (SOC) arm of SLS compared with the UK population of COPD patients.To compare the rates of COPD exacerbation, and of serious pneumonia, over the 12 months in SoC arm of the SLS compared with the SOC recorded in the CPRD.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

RELVAR

Medical condition to be studied

Chronic obstructive pulmonary disease

Population studied

Short description of the study population

Two cohorts will be produced. First, a CPRD cohort, using linked primary care, medication, Hospital Episode Statistics, and socio-economic data, according to the
following inclusion criteria:

I. Diagnosis of COPD before index date (time period will be defined in the SAP)

2. Aged 240 at index date.

3. Alive, and registered with a GP, at index date.

4. Not registered with a GP in the Greater Manchester area.

Second, a Salford cohort will be constructed using the Salford Integrated Record (SIR), according to the inclusion criteria:

1. Diagnosis of COPI) before index date.

2. Aged 240 at index date.

3. Alive, and registered with a GP, at index date.

Restricted cohorts will then be constructed in both the Salford and CPRD populations, based on the inclusion/exclusion criteria and study period for the SLS:

1. Patients with documented GP diagnosis of COPD, and currently receiving maintenance therapy

2. Male or female subjects aged 240 years of age at index date

3. Patients who have a history of treatment with systemic/oral corticosteroids, antibiotics (in association with GP contact) and/or hospitalisation for at least one COPI) exacerbation in the 3 years prior to index date.

4. Current COPD Therapy

All patients currently receiving either:

- inhaled corticosteroid (ICS) alone or in combination with a long acting bronchodilator (this could be a fixed dose combination or an ICS/LABA provided in two separate inhalers, or ICS and LAMA),
- or long-acting bronchodilator therapy alone (e.g. tiotropium or salmeterol, or the use of two bronchodilators i.e. LABA/LAMA),
- or "triple therapy" i.e. ICS/LABA plus a Long Acting Muscarinic Antagonist (LAMA)
Finally, the third data source, the SLS, will be used as-is.

Exclusion Criteria
Subjects meeting any of the following criteria must not be included in the restricted cohorts:
1. Patients with any life threatening condition or uncontrolled/clinically significant disease (code list to be specified in the Study A

Age groups

- 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)

Estimated number of subjects

30.000

Study design details

Outcomes

Rate of COPD exacerbation: The definition of a COPD exacerbation to be informed by the ongoing study being conducted by Jenny Quint et al. (collaborative project between London School of Hygiene and Tropical Medicine and GSK, GSK study number WEUSKOP5893).Serious Pneumonia: see Table 1 of protocol. • Healthcare utilisation: All GP visits/encounters and all hospital admissions during the 12 month follow-up.• Adherence to index prescription• Deaths: All cause, pneumonia death, COPD-attributed death.• Other definitions of COPD exacerbation: Other definitions will be described as per the outputs of study WEUSKOP5893.

Data analysis plan

Multilevel modelling with indicator of SLS versus CPRD membership as exposure.

Documents

Study results

Additional information for 201491.pdf (92.6 KB)

gsk-201491-clinical-study-report-redact.pdf (9.44 MB)

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

CoI of investigators.pdf (375.7 KB)

Composition of steering group and observers

CHESS scientific committee.pdf (218.17 KB)

Data sources

Data source(s)

Clinical Practice Research Datalink

Data source(s), other

Salford Lung Study (SLS) trial data United Kingdom, SIR

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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