

# 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.

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## 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

[Pharma.CDR@gsk.com](mailto:Pharma.CDR@gsk.com)

### Primary lead investigator

Sperrin Matthew

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 10/03/2015

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### Study start date

Planned: 02/04/2012

Actual: 23/10/2015

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### Data analysis start date

Planned: 04/01/2016

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### Date of interim report, if expected

Planned: 10/05/2016

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### 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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**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

**Name of medicine**

RELVAR

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**Medical condition to be studied**

## 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:

1. 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

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### 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)

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### Estimated number of subjects

30000

## 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.

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### **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)

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## **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**

[Col of investigators.pdf](#) (375.7 KB)

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### **Composition of steering group and observers**

[CHESS scientific committee.pdf](#) (218.17 KB)

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## Data sources

### **Data source(s)**

Clinical Practice Research Datalink

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### **Data source(s), other**

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

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### **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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No