EXPLORING THE BIDIRECTIONAL RELATIONSHIP BETWEEN DATABASE MARKERS OF ASTHMA TREATMENT ADHERENCE AND ASTHMA-RELATED OUTCOMES (ICS ADHERENCE & ASTHMA CONTROL OUTCOMES)

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Study Finalised

Administrative details

EU PAS number

EUPAS4891

Study ID

34622

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The study will be a prospectively-planned observational study using electronic medical records collected from primary care practices in the United Kingdom to explore to what extent and in what contexts adherence may be considered an asthma outcome, or/and a predictor of asthma outcomes by conducting an observational study designed to investigate the bi-directional relationship between database markers of asthma treatment adherence and asthma control.

Study status

Finalised

Research institutions and networks

Networks

Respiratory Effectiveness Group (REG)

☐ Belgium
☐ Denmark
☐ France
☐ Germany
☐ Greece
☐ Hungary
☐ Italy
☐ Netherlands

☐ Spain

☐ Sweden

☐ United Kingdom

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Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gene Colice

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2013

Actual: 23/01/2014

Study start date

Planned: 03/03/2014

Actual: 10/03/2014

Date of final study report
Planned: 01/07/2014

Actual: 01/07/2018

Sources of funding

- Other

More details on funding

Respiratory Effectiveness Group (REG)

Study protocol

Adherence study protocol_REG_15Jan2014_ADEPT approved.pdf(1.1 MB)

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:

Effectiveness study (incl. comparative)

Other

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

Adherence - asthma control interaction analysis

Data collection methods:

Secondary use of data

Main study objective:

To explore to what extent and in what contexts adherence may be considered an asthma outcome, or/and a predictor of asthma outcomes by conducting an observational study designed to investigate the bi-directional relationship between database markers of asthma treatment adherence and asthma control

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients.

Patients must meet the following inclusion criteria:

1. Have 3-years of continuous medical records, including 1 year prior to the IPD and 2 years after the IPD.

2. Received a physician-diagnosis of asthma (i.e. recorded diagnostic, Read Code) at least one year prior to the IPD.

3. Aged ≥6 years at IPD (i.e. ≥5 years at time of recorded asthma diagnosis)

4. At the IPD, received their first prescription* for an ICS (any) delivered via metered dose inhaler (MDI) or dry powder inhaler (DPI)

5. On active asthma therapy (defined as ≥2 prescriptions for ICS and/or SABA at different points in time during each of the two outcome years).

Age groups

Children (2 to < 12 years)

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

50000

Study design details

Outcomes

Database markers of adherence –prescription-based refill ratesComposite database markers of asthma controlModerate/Severe exacerbation (composite measures)SABA usage (proxy symptoms)Treatment stability (i.e. database marker of control and no use of additional therapy)

Data analysis plan

Phase 1, longitudinal evaluation: Descriptive analysis of adherence, asthma outcomes and confounders over the study periodPhase 2: Cross-lagged panel design – SEM models of asthma adherence and outcomes: Associations between adherence and each outcome (in a cross-lagged panel analysis) using the number of time intervals selected in Phase 1.Phase 3: 3.Hierarchical longitudinal models – separate MLM models of adherence (MPR) and asthma outcomes: Predictors of between- and within-subject variance in adherence and outcomes will be explored via hierarchical longitudinal models. If possible, adherence and outcome variables will be coded both as simultaneous and as lagged measurements in separate models, to examine both types of relationships. Time-varying predictors will be recoded to distinguish between individual mean levels and within-person deviations from individual means

Documents

Study publications

Souverein PC, Koster ES, Colice G, Van Ganse E, Chisholm A, Price D, Dima AL, R...

Vervloet M, van Dijk L, Spreeuwenberg P, Price D, Chisholm A, Van Ganse E, Pinn...

Data management

Data sources

Data source(s)

Optimum Patient Care Research Database

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, The Optimum Patient Care Research Database (OPCRD). OPCRD contains all records from primary care practices in the UK who subscribe to the Optimum Patient Care (OPC) respiratory review. The dataset consists of both routine primary care electronic patient records + patient-reported questionnaire data (for a subset of patients who completed disease-specific questionnaires as part of the review).

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