Does the cost of inhaler devices affect therapy adherence and disease outcomes?

First published: 26/05/2016

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS13586

Study ID

17441

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The aim of the study is to investigate whether a raise in prescription costs affects maintenance therapy and disease outcomes in patients with asthma or COPD. The objectives are to characterise patients who pay prescription charges

and those who do not (i.e. HSE medical card holders) in an Irish primary care population diagnosed with asthma or COPD and for both groups to assess whether maintenance therapy adherence and disease control is better in patients who do not pay prescription charges compared to those who do pay.

Study status

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/06/2016

Actual: 09/06/2016

Study start date

Planned: 17/06/2016

Actual: 04/11/2016

Data analysis start date

Planned: 29/07/2016

Actual: 04/11/2016

Date of interim report, if expected

Planned: 15/08/2016

Actual: 11/11/2006

Date of final study report

Planned: 01/11/2016

Actual: 23/11/2016

Sources of funding

- Other

More details on funding

RIRL, DASG

Study protocol

20160526_R00315 Cost of inhaler devices Protocol_swym.pdf (798.92 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To find if free prescriptions influences adherence to asthma and COPD treatment

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

Irish primary care population diagnosed with asthma/COPD with ≥ 1 prescription for SABA (short-acting beta2-agonist)/SAMA (short-acting

muscarinic antagonist), LABA (long-acting beta2-agonist)/LAMA (long-acting muscarinic antagonist) or ICS (inhaled corticosteroids) prior to the index date.

Age groups

- Infants and toddlers (28 days – 23 months)
- 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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

150

Study design details

Outcomes

Adherence to maintenance asthma and COPD therapy, Risk domain asthma controlNumber of severe exacerbationsAcute respiratory eventsSABA reliever usage

Data analysis plan

Baseline differences across the study cohorts will be analysed to look for differencesThe proportion of patients who are considered adherent (>80% refill rate) will be compared between the free prescription and the paying group. A difference of 25% will be considered significant.Secondary outcomes will be compared using chi square and wilcoxon tests as appropriate.

Documents

Study results

161123_R00315_Final_report.pdf (4.24 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.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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