

# 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.

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## 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

Jaco Voorham jaco@opri.sg

Study contact

## Primary lead investigator

David Price

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 09/06/2016

Actual: 09/06/2016

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### Study start date

Planned: 17/06/2016

Actual: 04/11/2016

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### Data analysis start date

Planned: 29/07/2016

Actual: 04/11/2016

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### Date of interim report, if expected

Planned: 15/08/2016

Actual: 11/11/2006

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### 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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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  $\geq 1$  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.

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### **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)

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### **Special population of interest**

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

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### **Estimated number of subjects**

150

## Study design details

### **Outcomes**

Adherence to maintenance asthma and COPD therapy, Risk domain asthma control  
Number of severe exacerbations  
Acute respiratory events  
SABA reliever usage

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## Data analysis plan

Baseline differences across the study cohorts will be analysed to look for differences. The 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)

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## Data management

## 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

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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