Training requirements to master inhaler devices available in real-life clinical practice (TMID)

First published: 09/03/2016

Last updated: 22/02/2024

Study | Planned

Administrative details

EU PAS number

EUPAS12321

Study ID

18084

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A prospective evaluation of time required and patient preferences when training patients with asthma and COPD to use inhaler devices as part of their routine care in the UK.

Study status

Planned

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

Lucy Wood

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2015

Actual: 01/10/2015

Study start date

Planned: 06/04/2016

Data analysis start date

Planned: 08/06/2016

Date of interim report, if expected

Planned: 19/09/2016

Date of final study report

Planned: 19/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Pharmaceutical Industries

Study protocol

R02615_TEVA_Training Requirements _Protocol_151217_V1.4.pdf (1.82 MB)

R02615_TEVA_Training Requirements _Protocol_170303_V1.5.pdf (1.87 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 type:

Non-interventional study

Main study objective:

To measure the time needed and number of attempts for patients with asthma and COPD to master the required inhaler technique for a specific delivery device available as part of their normal care.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Asthma

Chronic obstructive pulmonary disease

Population studied

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

204

Study design details

Outcomes

Time taken to achieve device mastery (as recorded in seconds from the beginning of training) and number of attempts to reach device mastery (please

see full protocol for details). After training and assessment on the devices, the patient will complete an inhaler device preference questionnaire developed by OPC and administered by the HCPs and/or service coordinator on the day of the iHARP asthma/COPD review clinic (please see full protocol for details).

Data analysis plan

Statistically significant results will be defined as $p<0.05$ and trends as $0.05 \leq p<0.10$. Summary statistics will be produced for all baseline and outcome variables, as a complete dataset and by inhaler device. The mean/median time required to achieve device mastery will be compared by using Cox regression analysis. Log-rank tests will be carried out and p-values reported. The mean/median number of attempts required to achieve device mastery will be compared by using a paired t-test (means) or Wilcoxon signed rank test (medians), dependent on the data distribution. Results from the patient preference questionnaire will be compared using a paired t-test or wilcoxon signed rank test depending on the data distribution. The 5% level of significance will be used (two-tailed test).

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 source(s)

Optimum Patient Care Research Database

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