Comparative Effectiveness of Extra-Fine Particle Inhaled Corticosteroid (ICS) and Alternative Guideline-Recommended Step-Up Options in Pre-School Children

First published: 17/08/2015
Last updated: 21/02/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/25899

EU PAS number
EUPAS10684

Study ID
25899

DARWIN EU® study
No

Study countries
United Kingdom

Study description
This will be a prospectively planned matched cohort study drawing on retrospective, electronic medical records from the Optimum Patient Care Research Database (OPCRD). The small particle size of extra –fine ICS may be particularly relevant for younger, preschool (<5 years) children, in whom a greater proportion of airways are classified as small. The aim of this study is to test the hypothesis that use of EF ICS in pre-school children (i.e. ?5 years of age) with asthma/wheeze will achieve better outcomes than treatment alternatives (i.e. NEF ICS, LTRA, or SABA) .

Study status
Ongoing

Research institution and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)
United Kingdom
First published: 06/10/2015
Last updated
23/11/2016

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

Networks

Respiratory Effectiveness Group (REG)
Belgium
Denmark
France
Germany
Greece
Hungary
Italy
Netherlands
Spain
Sweden
United Kingdom
First published: 07/07/2021
Last updated
04/06/2024

Network | 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:
30/08/2015

Study start date
Planned:
01/09/2015
Actual:
24/09/2015

Data analysis start date
Planned:
09/10/2015

Date of final study report
Planned:
06/05/2016

Sources of funding

- Other

More details on funding

REG

Study protocol

RESEARCH PROTOCOL REG_EF ICS in preschool children_v4.pdf(1.02 MB)

Regulatory

Was the study required by a regulatory body?
Unknown

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Effectiveness study (incl. comparative)

Main study objective:
The aim of this study is to test the hypothesis that use of extra-fine ICS in pre-school children (i.e. ?5 years of age) with asthma/wheeze will achieve better outcomes than treatment alternatives (i.e. non extra-fine ICS, LTRA, or SABA).

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Observational, matched cohort study drawing on retrospective, EMRs from the OPCRD

Study drug and medical condition

Medical condition to be studied
Asthma

Population studied

Age groups
Children (2 to < 12 years)

Estimated number of subjects
11000

Study design details

Outcomes
Exacerbations (ATS/ERS definition) defined as occurrence of an: • Asthma-related: Hospital admissions OR A&E attendance, OR• An acute course of oral steroids (coded for asthma or wheeze). -Acute respiratory event-Risk Domain Asthma Control -Overall Asthma Control (OAC)-Treatment stability-SABA usage-Controller-to-Reliever Ratio-Oral Thrush

Data analysis plan
Statistically significant results will be defined as p<0.05 and trends as 0.05?p<0.10. Summary statistics will be presented as appropriate for each variable: • Variables measured on the interval or ratio scale: n and % of non-missing data, mean (standard deviation) and median (inter-quartile range)• Categorical variables: n (%) of non-missing data, n (%) per categoryTreatment cohorts were compared at baseline using the Mann–Whitney test for continuous variables and the Chi-squared test for categorical variables.Conditional logistic regression will be used to compare baseline characteristics between matched cohorts. Any variables that remained potentially different between matched cohorts at baseline (p<0.10) will be included as potential confounding factors in the outcome analysis. Conditional logistic regression will be used to compare cohorts for binary outcomes, and a conditional Poisson regression model will be used to compare outcome exacerbation rates.

Data management

Data sources

Data source(s), other
OPCRD United Kingdom

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