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

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 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

Networks

Respiratory Effectiveness Group (REG)

- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

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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 $0.05 \leq p<0.10$. 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

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), 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