REDS (REspiratory Drugs Survey) STUDY. Active surveillance of respiratory drugs, especially Inhaled Steroids (IS) in children (REDS STUDY)

First published: 10/02/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12410

Study ID

28894

DARWIN EU® study

No

Study countries

Italy

Study description

Despite the prevalence of Asthma has settled down to between 9.5 and 10.5% in children aged 6 to 11 years, it has been particularly noted that IS (beclomethasone, budesonide, flunisolide, fluticasone, etc.), are used inappropriately in children with an "over prescription" for conditions that do not require their use. Despite being an anti-asthmatic medicine, it is often prescribed for colds, coughs and sore throats. In the Enbe Study (Effectiveness of beclomethasone versus placebo in the treatment of preventing viral wheezing in the pre-school age group) beclomethasone reduced the risk of viral wheezing by 4% (from 11 to 7%) but the difference was not statistically significant. The results of Enbe confirms data already highlighted by some studies: that the IS has a modest effectiveness in preventing both recurrent wheezing viral and that of respiratory syncytial virus infections (bronchiolitis) in the child. In addition, no benefits were noted in reducing symptoms of infection to the respiratory tract. Therefore a more rational effort is needed regarding these pharmaceuticals both by doctors and above all by parents who frequently administer medicines to children for infections of the respiratory tract, without consulting their pediatrician. Phase IV research project will be conducted by Family Pediatricians (FP) that can foresee on the one hand, training courses for FP and informational for families regarding the correct use of respiratory medication the ISs any iatrogenic illness caused by their improper use, on the other hand which may constitute a territorial survey on prescriptive appropriateness and safety of these pharmaceuticals in children aimed at evaluating the risk-benefit balance on usage.

Study status

Finalised

Research institutions and networks

Institutions

FP-MCRN

Networks

Family Pediatricians - Medicines for Children Research Network (FP-MCRN)

Italy

First published: 18/03/2010

Last updated: 03/01/2019

Network | Outdated | ENCePP partner

Contact details

Study institution contact

Ettore Napoleone ettorenapoleone@tiscali.it

Study contact

ettorenapoleone@tiscali.it

Primary lead investigator

Ettore Napoleone

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 29/01/2016

Actual: 29/01/2016

Study start date
Planned: 11/10/2016

Actual: 11/10/2016

Data analysis start date
Planned: 11/10/2018

Actual: 11/10/2018

Date of interim report, if expected
Planned: 11/03/2018

Actual: 11/03/2018

Date of final study report
Planned: 11/02/2019

Actual: 11/03/2019

Sources of funding

- Other

More details on funding

AIFA (ITALIAN MEDICINES AGENCY)

Study protocol

REDS engl.pdf (178.94 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the study is monitoring the use of respiratory medication and in particular the IS with careful analysis of the risk / benefit

factor of the therapy (for possible ADRs) in the age group from 0 to 14 years, through: 1) Accuracy of diagnosis,2) Therapeutic Appropriateness,3) Safe use of medication,4) Correct follow-up

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R01A) DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Medical condition to be studied

Childhood asthma

Population studied

Short description of the study population

Children of both sexes, aged between 0 and 14 years suffering from illnesses (asthma, etc.) who were foreseen to be using respiratory medication and in particular the IS in compliance with the Guidelines.

Age groups

- Term newborn infants (0 – 27 days)

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

3000

Study design details

Outcomes

- Evaluate the effectiveness of the therapy in the acute phase according to the GL. - Reduce the number of pharmaceutical respiratory prescriptions (especially IS) - Check and give a correct estimate of possible ADRs associated with this type of medication administered by Family Pediatricians - Increase the number of reported ADRs - Decrease the "do it yourself" by parents

---

Data analysis plan

The data of prevalence of prescriptions of IS iN children and any ADRs related to the use of IS will be highlighted. Safety usage- calculating the impact of ADRs in the population at risk taking part in the research, until the risk assessment of some ADRs are compared and associated with specific pharmaceuticals within groups. The univariate statistical analysis and description of the characteristics of the sample will produce frequencies, medians and interquartile range for variable nonparametric and medium ± standard deviation for parametric variables. The confidence intermissions at 95% will be calculated where possible. The bivariate analysis for variable categorical will be produced using the two-tailed $\chi 2$ test and when appropriate, the Fisher corrector will be used, for numeric variables, any differences in averages between groups will be assessed by the student's t-test. Statist. significance is defined by a value of P

<0.05 and will be calculated at 95% C.I-R version2.13.0

Documents

Study results

Results REDS.pdf (419.75 KB)

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

decl of Inter.pdf (1.38 MB)

Composition of steering group and observers

SC.pdf (27.85 KB)

Signed code of conduct

2016-0037-DoC COC-SDPP-12410.pdf (407.69 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

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

Unknown