Increasing ICS Dose vs Add-on Therapy in Children with Asthma (Paediatric Asthma Step-up)

First published: 31/07/2015

Last updated: 31/07/2015

Study Finalised

Administrative details

EU PAS number

EUPAS10483

Study ID

10484

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A historical observational database study UK using primary care data to evaluate the comparative effectiveness of different paediatric asthma step-up options with respect to asthma control at 12 months, specifically ICS dose increase, addition of LABA to existing ICS (as either a separate inhaler or as part of a fixed dose combination) or the addition of LTRA to existing LABA therapy.

Study status

Finalised

Research institutions and networks

Institutions

Research in Real Life

First published: 01/02/2024

Last updated: 01/02/2024

Institution

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

Stephen Turner

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/12/2012

Actual: 03/12/2012

Study start date
Planned: 07/01/2013

Actual: 07/01/2013

Date of final study report
Planned: 15/07/2015

Actual: 15/07/2015

Sources of funding

- Other

More details on funding

Respiratory Effectiveness Group, Research in Real Life Ltd

Study protocol

GPRD Prescribing Protocol Final Version 2_ENCePP.pdf (748.4 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary focus is to investigate the relationship between a step-up in asthma treatment (i.e. addition of a long-acting β-agonist (LABA), leukotriene receptor antagonist (LTRA) or increased ICS dose) in children aged 5-12 and the impact on asthma control over a 12 month period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(H02) CORTICOSTEROIDS FOR SYSTEMIC USE

CORTICOSTEROIDS FOR SYSTEMIC USE

(R03DC) Leukotriene receptor antagonists

Leukotriene receptor antagonists

(R03) DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Asthma patients on inhaled corticosteroid therapy (any ICS) between January 1990 and the end of December 2010 (2011).

Age groups

- Children (2 to < 12 years)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

17.000

Study design details

Outcomes

Exacerbation Rate (ATS/ERS Definition) Where an exacerbation is defined as the occurrence of: (i) Asthma-related1: a. Hospital attendance / admissions OR b. A&E attendance (ii) Use of acute oral steroids2, Database Asthma Control, defined as:the absence of the following during the one-year outcome period:(i) Asthma-related: Hospital admission, A&E attendance, Out of hours attendance, Out-patient department attendance (ii) GP consultations for lower respiratory tract infection(iii) Prescriptions for acute courses Additional secondary measures:Hospitalisations, Adherence,SABA usage

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Data analysis plan

Patients will be characterised over a 1-year baseline period. For outcome evaluation, patients will be matched on on key clinical and demographic features to minimise differences between treatment arms and to minimise the risk of confounders. Remaining differences will be adjusted for using suitable statistical modelling.Both unmatched and matched results will be reported, as well as matched results adjusted and unadjusted for residual confounders.

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)

Clinical Practice Research Datalink

Data source(s), other

Optimum Patient Care Research Database (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