Study of evidence of potential selective prescribing of clenbuterol compared to other beta-2-agonists (Clenbuterol selective prescribing)

First published: 24/04/2020

Last updated: 24/04/2020

Study Finalised

Administrative details

EU PAS number

EUPAS34901

Study ID

34902

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Patients with a first prescription for a beta-2-agonist and at least 180 days of observation were considered. Respiratory diagnoses on the date of the first prescription, and events in the history of the patients were identified that may suggest that clenbuterol is selectively prescribed for purposes of muscle building, weight management or sports, or to patients at risk of abuse.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/03/2020

Actual: 26/03/2020

Study start date
Planned: 26/03/2020

Actual: 26/03/2020

Data analysis start date
Planned: 26/03/2020

Actual: 26/03/2020

Date of final study report
Planned: 23/04/2020

Actual: 23/04/2020

Sources of funding

- EMA

Study protocol

Clenbuterol.pdf(285.29 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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The aim of the study was to identify baseline risk factors and indications for use at first start of treatment with clenbuterol vs. other selective beta-2-agonists that may suggest that clenbuterol is selectively prescribed for purposes of

muscle building, weight management or sports, or to patients at risk of abuse.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03AC) Selective beta-2-adrenoreceptor agonists

Selective beta-2-adrenoreceptor agonists

Population studied

Short description of the study population

Patients with a first prescription for a beta-2-agonist and at least 180 days of observation were considered.

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

500000

Study design details

Data analysis plan

Proportion of patients with selected diagnoses among patients that initiated treatment with clenbuterol vs. patients that initiated treatment with other beta-2-agonists. Descriptive study.

Data management

Data sources

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