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

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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)

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Institution

Contact details

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Primary lead investigator

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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

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 sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Unknown			
Check completer	ness		
Unknown			

Check stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No