Pattern of use of Human Growth Hormone (Somatropin) in the United Kingdom general practice setting: A Drug Utilization Study in The Health Improvement Network (THIN) database (Somatropin use in routine clinical practice in UK)

First published: 03/03/2011

Last updated: 19/07/2016

Study Finalised

Administrative details

EU PAS number

EUPAS1821

Study ID

14166

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The study describes the pattern of use of the Recombinant Human Growth Hormone (somatropin) over two decades in patients selected within the UK primary care setting. Namely: • Indications for somatropin • Demographic and clinical characteristics of the treated population • How the clinical profile of somatropin users compare to that of the general population• Pattern of dosage and duration of therapyThe study population includes new users of somatropin between 1 January 1990 and 30 May 2010. Only permanent patients with a minimum of 6 months' registration with the practice at the time of the first prescription are included.This is a retrospective analysis of somatropin users selected in The Health Improvement Network (THIN) database. The Network collects pseudo-anonymised electronic medical records of patients managed in the UK primary care setting. Comprehensive patient-level data include diagnostic codes, prescriptions and other health-relevant patient information. Clinical characteristics of treated patients are compared to those of a random sample of untreated patients matched on age and sex to treated patients. Study measures include:• Frequency distribution of study population by sex, age groups and indications, including: GH deficiency, Turner syndrome, chronic renal insufficiency, Prader-Willi syndrome, small at birth for gestational age, other indication • Frequency distribution of dosage at start of therapy and of average length of treatment• Prevalence of major co-morbidities, such as endocrine, cardiovascular, and respiratory diseases, and neoplasmsCategorical data are presented as number and percentage of patients, continuous data are summarized by the number of patients, mean, standard deviation, median, lower and upper quartiles, minimum and maximum values. Where appropriate, two-sided 95% confidence intervals are presented. Statistical testing is reported using a 2-sided significance level of 0.05

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

Annalisa Rubino

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2010

Actual: 01/12/2010

Study start date

Planned: 01/12/2010

Actual: 01/12/2010

Date of final study report

Planned: 28/03/2011

Actual: 28/03/2011

Sources of funding

- EMA

Study protocol

GH_protocol_v1.pdf(188.5 KB)

Regulatory

Was the study required by a regulatory body?

No

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:

To describe the pattern of use of somatropin in patients selected within the UK primary care setting. Namely: • Indications for somatropin • Demographic and clinical characteristics of the treated population • How the clinical profile of somatropin users compare to that of the general population• Pattern of dosage and duration of therapy

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

SOMATROPIN

Population studied

Short description of the study population

Patients prescribed with somatropin between January 1, 1990 and May 30, 2010, permanent patients with a minimum of 6 months’ registration with the practice at the time of the first prescription

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Age groups

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

1200

Study design details

Data analysis plan

All analyses will be conducted using SAS Enterprise Guide version 4.1. All analyses will be presented for all patients and separately by indication subgroup, in particular for the group of children with idiopathic GH deficiency.Categorical data will be summarised by the number and percentage of patients in each category. Continuous data will be summarised by the number of patients, mean, standard deviation, median, minimum and maximum values. Where appropriate, two-sided 95% confidence intervals will be presented. Any statistical testing will be reported using a 2-sided significance level of 0.05 for each analysis or, when equivalence is asserted, using

confidence intervals.Any difference in clinical characteristics of somatropin versus control patients will be examined with chi square tests. Summaries will also be provided for age sub-groups of patients, as appropriate.

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

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