ESTUDIO AUXOGROWTH - Estudio Exploratorio para la Utilización del Programa de Crecimiento AuxoLog en Pacientes con Déficit de Hormona de Crecimiento tratados con Hormona de Crecimiento Recombinante Biosimilar

First published: 10/10/2014

Last updated: 14/04/2016

Study Finalised

Administrative details

EU PAS number

EUPAS7654

Study ID

13146

DARWIN EU® study

No

Study countries

Spain

Study description

The auxological parameters of GHD children treated with rhGH are compared with the countries specific growth standards and charts. Those are standardized and regular applied to all children in a unified manner, not attending to specific differences and allocation in differentiated growth groups.Nevertheless the development of children is not homogeneous and especially at the time of puberty, differences arise particularly in the age of pubertal onset, the time of pubertal growth spur and the rate of pubertal growth. Therefor the classification of children according to their pubertal group is of major importance, since children with a late or very late pubertal growth spur onset may be misdiagnosed as non-responders to rhGH and prematurely suspend their treatment, preventing them from reaching their full potential height.The Auxogrowth study intends to include the date of pubertal/post pubertal Spanish children treated with Omnitrope® on the AuxoLog program in order to evaluate their growth.It will include pubescent or post-pubescent children with GHD treated with Omnitrope® for at least two years before the onset of puberty with data available from at least one GH production stimulation test.Its objectives are to assess the increase in stature and growth rate in pubertal/post pubertal GHD children treated with Omnitrope® for a minimum of two years and to classify them according to time of pubertal development. The study will use the online AUXOLOG database program to conduct the work.AUXOLOG is a program that facilitates assessment of auxological parameters data and determination of growth patterns in children.

Study status

Finalised

Research institutions and networks

Institutions

University Hospital Vall d’Hebron (HUVH)

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Hospital Universitario Virgen del Rocío

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Institution

Hospital Universitario Virgen del Rocío Seville, Spain, Hospital universitario Puerta del Mar Cádiz, Spain, Hospital San Pedro Logroño, Spain

Contact details

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Study contact

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Primary lead investigator

Antonio Carrascosa

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/03/2014

Actual: 17/03/2014

Study start date

Planned: 01/09/2014

Actual: 10/10/2014

Data analysis start date

Planned: 01/10/2015

Date of final study report

Planned: 01/04/2016

Actual: 14/04/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sandoz Farmacéutica

Study protocol

Protocolo Auxogrowth v4.pdf(842.56 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:

Assess the increase in stature (height, standard deviation (SD) of height), growth rate (GR) and standard deviation of growth rate (SDGR) in GHD children treated with Omnitrope® for a minimum of two years.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series, Observational, retrospective

Study drug and medical condition

Name of medicine

OMNITROPE

Medical condition to be studied

Growth hormone deficiency

Population studied

Short description of the study population

Patients with Growth hormone deficiency.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Special population of interest

Other

Special population of interest, other

Patients with Growth hormone deficiency

Estimated number of subjects

30

Study design details

Outcomes

HeightStandard deviation (SD) of height,Growth rate (GR)Standard deviation of growth rate (SDGR), Identify the time of pubertal development

Data analysis plan

Absolute frequencies will be reported as a summary (n) and relative frequencies as a percentage (%), 95% confidence intervals (CI) will be also given. The ‘normality’ of quantitative variables will be checked with the Kolmogorov-Smirnov test, normally distributed variables will be then summarised using the mean and standard deviation. In all analyses, a significance level below 0.05 was established (95% confidence).

Documents

Study results

CLINICAL STUDY REPORT SDZ Global.pdf(1.12 MB)

Study report

CONTRATO FINAL FIRMADO (PTE FIRMA RESTO DE PAGINAS IP).pdf(413.03 KB)

Study, other information

Anexo 5.1 APROBACION DEL CEIC.pdf(25.93 KB)

ANEXO 5.2 APROBACION CEIC REF..pdf(89.54 KB)

Anexo 5.3 CLASIFICACION AGENCIA.pdf(184.95 KB)

CONTRATO FINAL FIRMADO_H PUERTA DEL MAR.pdf(430.42 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.

Data sources

Data sources (types)

Other

Data sources (types), other

Hospitals patient registry - paediatric

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