

# Follow-up of adult patients treated with growth hormone NUTROPIN Aq® (Nutropin in Adults)

**First published:** 13/11/2014

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7944

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### Study ID

30183

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### DARWIN EU® study

No

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### Study countries

France

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### Study description

The objectives of this observational study are: - Define the profile of patients treated with NutropinAq® and describe the conditions for initiation and follow-up of treatment - Assess the safety of NutropinAq® in adults - Collect data on the quality of life of adults treated with NutropinAq®.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Ipsen Pharma**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

**Multiple centres: 55 centres are involved in the study**

## Contact details

### **Study institution contact**

Ipsen Medical Director [clinical.trials@ipsen.com](mailto:clinical.trials@ipsen.com)

**Study contact**

[clinical.trials@ipsen.com](mailto:clinical.trials@ipsen.com)

**Primary lead investigator**

Ipsen Medical Director

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 01/02/2005

Actual: 01/02/2005

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**Study start date**

Planned: 12/04/2005

Actual: 12/04/2005

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**Data analysis start date**

Planned: 29/12/2009

Actual: 29/12/2009

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**Date of final study report**

Planned: 30/06/2014

Actual: 07/07/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Ipsen Pharma

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Data collection methods:**

Primary data collection

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**Main study objective:**

The objectives of this observational study are: - Define the profile of patients treated with NutropinAq® and describe the conditions for initiation and follow-up of treatment - Assess the safety of NutropinAq® in adults - Collect data on the quality of life of adults treated with NutropinAq®.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational Model :Case-only

## Study drug and medical condition

**Medicinal product name**

NUTROPINAQ

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

SOMATROPIN

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**Anatomical Therapeutic Chemical (ATC) code**

(H01AC01) somatropin

somatropin

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## **Additional medical condition(s)**

Somatotrope deficit

# Population studied

## **Short description of the study population**

Adult patients treated with growth hormone NUTROPIN Aq®.

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## **Age groups**

- 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)
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## **Estimated number of subjects**

205

# Study design details

## **Outcomes**

Profile of patients treated with NutropinAq® and conditions for initiation and follow-up of treatment, Safety of NutropinAq® in adults. Quality of life of adults treated with NutropinAq®.

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## **Data analysis plan**

Descriptive analysis of all collected data at the baseline and follow-up visits according a statistical plan validated by authorities

## 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

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown