

ZOMAJET - Evaluation of Overall Compliance and Duration of Zomacton® Treatment With the Zomajet® Needle-free Device (ZOMAJET)

Head :Bahbah Farah

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General

Identification

Detailed name	Evaluation of Overall Compliance and Duration of Zomacton® Treatment With the Zomajet® Needle-free Device (ZOMAJET)
Sign or acronym	ZOMAJET
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	907122 (CNIL)

General Aspects

Medical area	Endocrinology and metabolism
Keywords	Somatropin, zomacton, zomajet vision X, Zomajet 2 vision

Scientific investigator(s) (Contact)

Name of the director	Bahbah
Surname	Farah
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Organization	FERRING

Collaborations

Funding

Funding status	Private
Details	Laboratory Ferring SAS

Governance of the database

Sponsor(s) or organisation(s) responsible Laboratoire FERRING SAS

Organisation status Private

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health institutions and services

Database recruitment is made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection. All patients, meeting the criteria of the Therapeutic Information Sheet (growth hormone deficiency or Turner's syndrome), for whom is initiated a treatment with Zomacton® 4 mg with the Zomajet® 2 Vision transjector or with Zomacton® 10 mg with the Zomajet® Vision X transjector when the latter has received its marketing authorization.

Database objective

Main objective Evaluate with sufficient precision the overall observance rate for the treatment over a maximum period of three years.

The study is carried out at the request of the authorities.

Inclusion criteria All patients, meeting the criteria of the Therapeutic Information Sheet (growth hormone deficiency or Turner's syndrome), for whom is initiated a treatment with Zomacton® 4 mg with the Zomajet® 2 Vision transjector or with Zomacton® 10 mg with the Zomajet® Vision X transjector when the latter has received its marketing authorization.

Population type

Age	Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	National
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2007
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Date of last collection (YYYY or MM/YYYY)	2011
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Size of the database

Size of the database (number of individuals)	< 500 individuals
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Details of the number of individuals	90
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Data

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data Paraclinical data Biological data
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Clinical data (detail)	Direct physical measures
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Declarative data (detail)	Face to face interview
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Paraclinical data (detail)	Auxological parameters (gain in size, etc.)
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Biological data (detail)	IGF-1 if available
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Presence of a biobank	No
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Health parameters studied

Health event/morbidity
Health care consumption and services

Care consumption (detail)

Medicines consumption

Procedures

Data collection method

Questionnaire at the initiation of the treatment (initiation visit): Identification of the questionnaire; visit date; inclusion criterion (Initial Therapeutic Information Sheet); patient data: sex, date of birth, height, weight, bone age (according to the Greulich-Pyle atlas), gain in size before treatment, pubertal stage (according to Tanner), antecedents; indication (deficit in GH or Turner's syndrome with karyotype), cause of the deficit in GH, exploration of the deficit in GH (IGF-1 if available, stimulation tests and results, associated hormonal or endocrine disruptions); Prescribed treatment; Dosage and methods of administration. Follow-up questionnaires (1 follow-up visit about every 3 to 6 months): Identification of the questionnaire; date of visit; height, weight, bone age, pubertal stage, fasting glucose and IGF-1 (if available); Treatment administered as prescribed (yes/no) - if not, treatment administered by intermittence, stopping of the treatment and reason(s) for noncompliance; Treatment stopped by the physician (yes/no) - if yes, date and reason(s) - if not, technical difficulties in using the pen (yes/no); modification in the methods of administration (yes/no): new dosage and/or new posology and/or new head for the transjector pen and reason(s). Local and general tolerance.

Participant monitoring

Yes

Details on monitoring of participants

minimum 1 year and 4 years total

Links to administrative sources

No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)

Clinical Report.
For further information on the ZOMAJET study, please contact: Dr Philippe NIEZ

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only