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 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)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	National

Data collection

Dates	
Date of first collection (YYYY or MM/YYYY)	2007
Date of last collection (YYYY or MM/YYYY)	2011

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

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

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 karyotope), 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