Growth disorders in Greece. Baseline data from a multicentre observational study (GeNeSIS).

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ABSTRACT

Aim The Genetics and Neuroendocrinology of Short Stature International Study (GeNeSIS) is an open-label multinational observational study which collects information on management, clinical outcomes and treatment safety of children with growth disorders. Here we present descriptive data from the Greek cohort.

Methods - Results In Greece, 211 children (44.5% females, 136 naive to GH treatment at study entry and 18 not GH-treated) have been enrolled, after providing informed consent, in 8 investigational sites, over 6 years (2005-2011). Growth hormone deficiency (GHD, N:177) and Turner syndrome (TS) (N:20) were the main diagnoses upon enrollment. GHD was diagnosed with higher frequency in males than females (63.5% vs. 36.5%). In patients where pubertal stage had been recorded, 70.4% of females (GHD 67.9%, TS 76.5%) and 78.3% of males were pre-pubertal (Tanner B1 and G1 respectively). The most frequently performed tests to confirm the need for GH administration were glucagon (40.0%) and clonidine (32.0%). When a combination test was performed glucagon and clonidine were paired most frequently (50%). The mean max GH peak was 6.1±3.1μg/L and 12.4±8.2 μg/L for patients with GHD and TS respectively. Baseline characteristics to be depicted in table. **Conclusions** In the Greek cohort of GeNeSIS, GHD is the most frequent cause for GH treatment, followed by TS. While the latter is diagnosed earlier, bone age to chronological age gap is numerically smaller and a higher GH initiation dose is administered. The results should be interpreted in the context of an observational, ongoing study.

AIMS

The Genetics and Neuroendocrinology of Short Stature International Study (GeNeSIS) is an

- open-label
- multinational
- observational study

on **management**, **clinical outcomes** and **treatment safety** of children with growth disorders.

Here we present **baseline** descriptive data from the **Greek** cohort of the GeNeSIS Study.

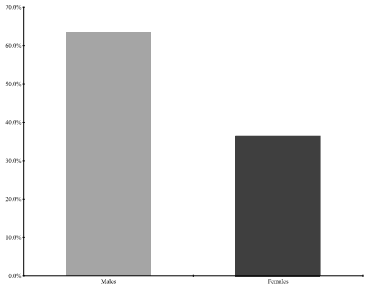
METHODS

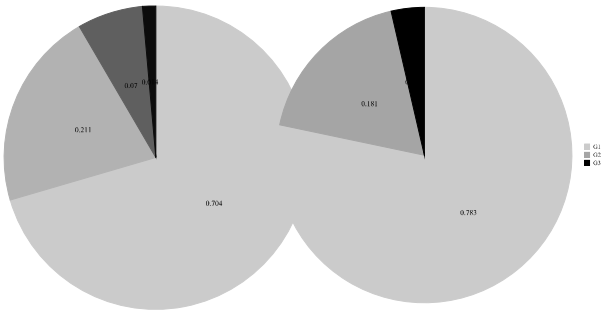
- In Greece, 211 children (44.5% females, 136 naive to GH treatment at study entry and 18 not GH-treated) have been enrolled, after providing informed consent, in 8 investigational sites, over 6 years (2005-2011).

RESULTS

Main diagnoses upon enrollment:

- Growth hormone deficiency (GHD, N:177, 151 idiopathic and 26 organic)
- SHOX deficiency (N:22, 20 Turner syndrome (TS) and 2 Leri-Weill syndrome)





Dynamic Tests most frequently performed to confirm the need for GH administration

- glucagon (40.0%) **- clonidine** (32.0%).

When a combination test was performed glucagon and clonidine were paired most frequently (50%).

Max GH peak after provocative tests:

Max GH_{GHD} peak: 6.1±3.1 μg/L Max GH_{TS} peak: 12.4±8.2 μg/L

Baseline characteristics		All [N=211]	GHD [N=177]	TS [N=20]
% females		44.5	37.3	100.0
CA (y) at baseline		10.0±3.4	10.1±3.4	8.8±3.0
Treated		193	167	20
First GH dose on study (mg/kg/wk)		0.17±0.07	0.16±0.06	0.29±0.06
TREATED PATIENTS	CA (y)*		10.0±3.4	8.8±3.0
	BAGP (y)*		8.3±3.3	7.9±3.3
	BA-CA (y)*		-1. 8±1.1	-0.9±0.8
	BAGP SDS*		-2.0±1.1	-1.1±1.0
	HtSDS*		-2.2±0.6	-2.2±0.8
	THSDS*		-0.7±0.7	-0.2±1.0
	HtSDS-THSDS*		-1.4±0.8	-2.0±1.0
	PreHV (cm/y)*		4.4±2.0	5.7±2.1
	PreHVSDS*		-1.3±1.5	-0.3±1.8
	Weight (Kg)*		29.6±12.1	28.1±8.4
	BMI SDS*		0.1±1.4	0.9±1.2
	Fasting glucose (mg/dL)*		82.9±7.9	86.0±9.1
	MaxGHpeak (μg/L)*		6.1±3.1	12.4±8.2
	IGF-I SDS *		-2.5±1.0	-2.2±1.0

* Numbers account for mean ± Standard Deviation(SD). Means calculated on recorded data which were not always available for the total population

CA: Chronological age, BAGP: Bone age by Greulich and Pyle, BA: Bone age, SDS: Standard Deviations, Ht: Height, TH: Target Height, PreHV: Predicted Height Velocity, BMI: Body Mass Index, GH: Growth Hormone, IGF-I: Insulin-like growth factor

BA-CA CIs(confident Intervals) -1.96 to -1.6 for GHD and -1.29 to -0.57 for TS

Initial Dose CIs 0.16 to 0.16 for GHD and 0.27 to 0.31 for TS

CONCLUSIONS

In the Greek cohort of GeNeSIS, **GHD** is the most frequent cause for GH treatment, followed by **TS**.
While the latter is diagnosed earlier, bone age to chronological age gap is numerically smaller and a higher GH initiation dose is administered.
The results should be interpreted in the context of an observational, ongoing study.

Sponsored by Pharmaserve-Lilly S.A.C.I.