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These results are supplied for informational purposes only. Prescribing decisions should be made based on the approved package insert in the country of prescription			
Sponsor/company:	sanofi-aventis	ClinicalTrials.gov Identifier:	NCT00476385
Generic drug name:	Somatropin	Study Code:	L_8912
		Date:	11-Feb-2009

Title of the study: Usability and acceptability of Stylomax® in growth hormone deficient children

Investigators:
Prof. David (69495 Pierre-Bénite, France)**,** Dr. Colle (33000 Bordeaux, France),
Dr. Stuckens (59037 Lille Cedex, France).

Study coordinator: Prof. David, Hôpital Lyon Sud, Service de pédiatrie, 69495 Pierre-Bénite, France.

Study Center(s):
Carried out at the pediatricians' and endocrinologists' place of practice.

Study period:	**Development phase:**
Part 1: June 2003 - July 2003	Phase III

Objectives: Evaluation of the usability and acceptability of injections performed with Stylomax® compared to conventional syringe injections in children previously treated with Maxomat®. Study of local and general safety and monitoring of specific hormone parameters (GH, IGF1, IGFBP3) after administration of this new presentation of Maxomat® which is more concentrated than the current presentation for injection, monitoring of growth after one year.

Methodology: Multicenter, open-label, nonrandomized trial, with direct individual benefit.

Number of patients: 12 patients included.

Diagnosis and main criteria for inclusion:

Inclusion criteria:
- Children of both sexes **over three years of age** with growth hormone deficiency according to the MA criteria, who have been treated with the growth hormone Maxomat® for at least one month.
- Informed consent must be signed by both parents or the legal guardian, and when possible, by the child.

Exclusion criteria:
- GH deficiency secondary to neoplastic disease,
- Mental retardation precluding replies to questionnaires,
- Any serious progressive disease.

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Investigational agent:	Stylomax® 6 Stylomax® 12
Posology:	Dosage reduced by 20% from the initial Maxomat® dosage
Dosage schedule:	One subcutaneous injection daily for four weeks, and then subsequent treatment according to the previous regimen, six or seven days a week.
Method of administration:	Subcutaneous
Duration of treatment:	Four weeks in the first part of the study, as described in this report, and 12 months for the whole study.

Criteria for evaluation:

Main criterion:
Usability / acceptability of the Stylomax® pen, with evaluation by the patient and parents of the following:

- Product reconstitution in the solvent cartridge,
- Use of the reconstitution system,
- Insertion of the cartridge into the Stylomax® pen,
- Attachment of the needle to the Stylomax® pen,
- Removal of air,
- Acceptability of STYLOMAX® pen: weight, dimensions, needle length.

Secondary criteria:

- Local and general safety: pain and reactions at the injection site (redness, bruising, pruritus).
- General preference between Maxomat® and Stylomax® treatments.
- Levels of GH, IGF1 and IGFBP3 with Maxomat® and Stylomax®.
- Growth

Statistical methods:

The statistical analysis is descriptive and in this report only concerns the results available for the first month of treatment:

- All data noted in questionnaires were collected and studied.
- The mean VAS score preceding the visit after the first month was calculated. A score was calculated for each patient.
- Laboratory results were evaluated.

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Summary:

Product reconstitution involved no difficulties in 10 out of 12 cases and the procedure for changing the needle was considered to be easy or very easy in all cases.

The injections were considered to have caused little or no pain in 11 out of 12 cases. The mean injection pain noted on the 100 mm visual analogue scale was lower with Stylomax® (10.1 mm with Stylomax® versus 28.9 mm with Maxomat®).
To the overall question comparing injections with Stylomax® and the syringe, 10 out of 12 children responded that the injections with Stylomax® were less painful than those with Maxomat®.

Local safety (assessed by the presence of bruising, pruritus, redness) was good in the majority of cases, although seven patients reported bruising.

Other advantages were noted: more injection sites available to the child, more precise injections, less anxiety for the child and faster injection, more autonomy for the child.

In addition, all the children wished to continue treatment with Stylomax®.

Measurements of hormone parameters confirmed the stability of GH levels (18.6 ng/ml versus 17.7 ng/ml), IGF1 levels (431.1 ng/ml versus 481 ng/ml) and IGFBP3 levels (2.8 ng/ml versus 2.9 ng/ml) whether the hormone was administered at the MA dosage using a needle, or at a 20% lower dosage using Stylomax®, due to the improved bioavailability related to this specific preparation.

Date of interim report: 4 September 2003