

Study of Growth-Promoting and Metabolic Effects of Growth Hormone (rhGH) (SGA)

This study is currently recruiting participants.

Verified by Assistance Publique - Hôpitaux de Paris, February 2009
 First Received: January 7, 2008 Last Updated: February 11, 2009 [History of Changes](#)

Sponsored by:	Assistance Publique - Hôpitaux de Paris
Information provided by:	Assistance Publique - Hôpitaux de Paris
ClinicalTrials.gov Identifier:	NCT00597480

▶ Purpose

Recombinant growth hormone (rhGH) treatment is widely used in France to normalize height during childhood and final height in children born small for gestational age (SGA). Because rhGH has been associated with increased insulin levels and insulin resistance, concern has been expressed regarding the late consequences of rhGH treatment on risk factors for **diabetes mellitus type II** and metabolic syndrome, especially in possibly predisposed subjects as SGA children.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Small for Gestational Age	Drug: rhGH (Norditropine SimpleXx®) Drug: rhGH norditropine simple Xx	Phase IV

[Drug Information](#) available for: [Somatropin](#) [Somatotropin](#)
[U.S. FDA Resources](#)

Study Type: Interventional

Study Design: Treatment, Randomized, Open Label, Active Control, Parallel

Design: Assignment, Safety/Efficacy Study

Official Title: Study of Growth-Promoting and Metabolic Effects of Growth Hormone (rhGH) by Comparison of Two Regimens of rhGH Administration to SGA Children.

Pharmacogenetics of Metabolic Responses to rhGH

Further study details as provided by Assistance Publique - Hôpitaux de Paris:

Primary Outcome Measures:

- identify and analyze factors implicated in the variability of the metabolic and growth responses to rhGH treatment in children born SGA.
[Time Frame: every three months during twenty seven months]
[Designated as safety issue: Yes]

Secondary Outcome Measures:

- Metabolic effects of rhGH treatment will be evaluated by body mass index (BMI), [Time Frame: every three months during]
[Designated as safety issue: Yes]
- Polymorphisms of different genes of the signaling pathway of GH and insulin
[Time Frame: the day of inclusion] [Designated as safety issue: No]

Estimated Enrollment: 100

Study Start Date: January 2008

Estimated Study Completion Date: January 2012

Estimated Primary Completion Date: January 2012 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
1: Active Comparator the recommended dose in the EU of rhGH (Norditropine SimpleXx®)	Drug: rhGH (Norditropine SimpleXx®) the recommended dose in the EU of rhGH (Norditropine SimpleXx®)
2: Active Comparator the dose to achieve a "treat-to target" value of IGF-1 levels within a +1,5 to +2,5 SDS interval (starting dose, 0,067	Drug: rhGH norditropine simple Xx the dose to achieve a "treat-to target" value of IGF-1 levels within a +1,5 to +2,5 SDS interval (starting dose, 0,067

mg/kg/day)	mg/kg/day)
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Detailed Description:

Recombinant growth hormone (rhGH) treatment is widely used in France to normalize height during childhood and final height in children born small for gestational age (SGA). Because rhGH has been associated with increased insulin levels and insulin resistance, concern has been expressed regarding the late consequences of rhGH treatment on risk factors for diabetes mellitus type II and metabolic syndrome, especially in possibly predisposed subjects as SGA children. Because rhGH use in this population will sharply increase in the coming years, our purpose is to identify and analyze factors that predispose these children born SGA to the metabolic consequences of rhGH therapy. The main objective of this study is to identify and analyze factors implicated in the variability of the metabolic and growth responses to rhGH treatment in children born SGA. We want to:

- Quantify the metabolic effects of rhGH treatment by analyzing insulin levels, insulin sensitivity and lipid profile (lipolysis and ketogenesis);
- Evaluate the effects of two different rhGH regimens on the growth of children born SGA;
- Determine if the metabolic effects of rhGH therapy correlate to the growth responses in the two groups;
- Identify factors, especially genetic factors, responsible for the variations in individual metabolic and growth-promoting effects of rhGH in children born SGA.

This is a randomized, open-labeled, 2-year study, which will compare two regimens of rhGH therapy on the growth responses and metabolic effects in short children born SGA. 100 prepubertal, non GH deficient, short children (height < -3 SDS) born SGA (birth height < -2 SDS) will be randomized to receive either the recommended dose in the EU of rhGH (Norditropine SimpleXx®), or the dose to achieve a "treat-to target" value of IGF-1 levels within a +1,5 to

- 2,5 SDS interval (starting dose, 0,067 mg/kg/day) for 24 months. Metabolic effects of rhGH treatment will be evaluated by body mass index (BMI), fasting insulin and glucose levels, HOMA index of insulin resistance, insulin and glucose levels during OGTT, HbA1C and fasting serum lipids (free fatty acids, 3-hydroxybutyrate, total cholesterol, LDL and HDL cholesterol, triglycerides). Height, growth velocity, IGF-1 and IGF-BP3 levels will evaluate growth response of rhGH treatment.

Polymorphisms of different genes of the signaling pathway of GH and insulin will be analyzed in order to search for those possibly responsible for the variability in metabolic and growth responses during rhGH treatment in SGA children.

► Eligibility

Ages Eligible for Study: 4 Years to 10 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- prepubertal age
- prepubertal characteristics
- non GH deficient
- short children (height < -2.5 SDS)
- born SGA (birth height < -2 SDS)
- parental height adjusted (< -1 DS)
- no rhGH treatment before inclusion

Exclusion Criteria:

- ALLERGY to rhGH or excipients
- small height etiologies
- cancer or cancer treatment ongoing
- drugs interference with growth
- mental impairment
- hypertrophic cardiopathy impairment
- hypertension not under controlled
- intra cranial hypertension not controlled
- diabetes and hyperglycaemia without diabetes
- dyslipidemia
- hepatitis
- kidney failure
- chromosomic aberration and/or genetic disorders (except Silver Russel Syndrome)
- no social security
- state of health in worst conditions after cardiac surgery, polytraumatism

▶ **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00597480

Contacts

Contact: Pierre BOUGNERES, MD, PHD 0033140488073 pierre.bougneres@paris5.inserm.fr

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Locations

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Sub-Investigator: Cecile Teinturier, MD

Recruiting

Sponsors and Collaborators

Assistance Publique - Hôpitaux de Paris

Investigators

Principal Investigator: Cecile Teinturier, MD AP-HP

▶ More Information

No publications provided

Responsible Party: Delegation of Clinical Research (Yannick VACHER)

Study ID Numbers: P070303

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Health Authority: France: Ministry of Health

Keywords provided by Assistance Publique - Hôpitaux de Paris:

Growth hormone

Child

insulin resistance

metabolic syndrome X

children born small for gestational age

Study placed in the following topic categories:

Metabolic Syndrome X

Hormones

Hormone Antagonists

Insulin

Hormones, Hormone Substitutes, and

Abdominal Obesity Metabolic Syndrome

Hormone Antagonists

Insulin Resistance

Additional relevant MeSH terms:

Physiological Effects of Drugs

Hormones, Hormone Substitutes, and Hormone Antagonists

Hormones

Pharmacologic Actions