

COLUMBIA UNIVERSITY MEDICAL CENTER

Unlocking the mysteries of HIV Treatment

Lipodystrophy Study: Growth Hormone (Serostim) and Rosiglitazone (Avandia)

You may be eligible if you;

- have increased fat in the belly, based on waist and hip measurements
- have insulin resistance based on a fasting insulin and glucose level do not have diabetes
- are currently on approved antiretroviral therapy

The study is 24 weeks long, divided into two 12-week parts.
Weeks 1-12: You will be assigned randomly to one of four groups:

1. Growth hormone (one injection, daily) plus rosiglitazone (one tablet, twice daily)
2. Growth hormone plus rosiglitazone placebo ("sugar pill")
3. Growth hormone placebo (plain water injection) plus rosiglitazone
4. Growth hormone placebo plus rosiglitazone placebo

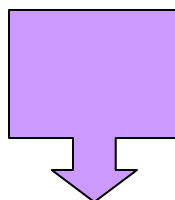
All participants will be hospitalized overnight for special tests at the beginning of the study and at week 12.

Week 13-24- All volunteers will receive both active drugs in this open-label phase.

**IRVING DIABETES RESEARCH UNIT
COLUMBIA UNIVERSITY MEDICAL CENTER**

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**LIPODYSTROPHY STUDY
Growth Hormone (Serostim) and Rosiglitazone (Avandia)**



A study testing the safety and effectiveness of growth hormone and rosiglitazone to reduce HIV-associated fat gain in people with insulin resistance.

A number of people who gain weight in the belly (lipodystrophy) also have a high level of the sugar-controlling hormone called insulin. These people need to produce this extra insulin to help keep their blood sugar normal. This is called "insulin resistance." Studies have shown that growth hormone (also called "Serostim") can decrease belly fat, but it can also worsen the insulin resistance. Rosiglitazone (also called "Avandia") is used to treat insulin resistance in people who have diabetes, so we want to see if taking growth hormone and rosiglitazone together will be better for treating lipodystrophy than either drug alone.

Growth hormone (one 2 mg injection, every other day) PLUS rosiglitazone (one 4 mg, twice daily).

Everyone in the study will need to be hospitalized overnight for special tests at the beginning of the study and at week 12.

The second part of the study is open-label, meaning that you and the study staff will know which drugs you are receiving. All volunteers will receive both active drugs.

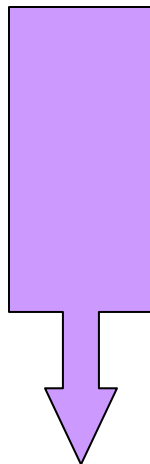
To be in this study, you must;

1. have excess abdominal (belly) fat, based on waist and hip measurements done at the screening visit.
2. Have insulin resistance, based on a fasting (no food for at least 8 hours) insulin and glucose level done at the screening visit.
3. Be on approved anti-HIV medications for at least 8 weeks.

For more information, call Dr. Daniel S. Donovan Jr., [Dr. Carlos R. Lopez](#) at

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Read more about eligibility



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Required:

- 18 - 85 years of age,
- HIV-infected and stable on FDA-approved antiretrovirals for at least 8 weeks,
- Excess abdominal fat based on waist and hip measurements done at the screening visit.
[Waist greater than 34.7 inches (men) or 29.6 inches (women) and waist to hip ratio greater than 0.5 (men) or 0.9 (women)].
- Evidence of insulin resistance (based on fasting glucose and insulin levels done at screening)
- Triglycerides less than 750 mg/dL,

Not allowed:

- Pregnancy,
- Active AIDS-defining infection or other acute illness, within 30 days of entry. • Active cancer (except for localized Kaposi's sarcoma) or active brain tumor.
- Any diagnosis of pancreatitis, carpal tunnel syndrome, diabetes, angina, coronary artery disease, or disorder associated with fluid retention (examples. cirrhosis. congestive heart failure).
- Untreated or uncontrolled high blood pressure, within 30 days of entry Within 12 weeks of study entry, use of the following:
 - Obesity (fat-reducing) drugs.
 - Anti-diabetic or insulin-sensitizing drugs (examples- rosiglitazone, pioglitazone, or metformin) • Systemic glucocorticoids (example. Prednisone),
 - Growth hormone or any medication for AIDS-associated wasting,
 - Systemic chemotherapy, interferon, or radiation therapy.
 - Androgenic agents [examples, nandrolone, oxandrolone (Oxandrin) (testosterone replacement therapy is permitted if started more than 30 days before entry)].
 - Appetite stimulants (Marinol, Megace, Peractin).
- Inability to have an MRI scan performed (examples: cardiac pacemaker, intracranial aneurysm clips).

Institutional Review Board (CPMCI/IRB)
IRB # AAA9622 Approval Date
initials CB Expiration Date
Columbia Presbyterian Medical Center