Follow the HIGH:low*
A follow-up study on the HIGH:low, a placebo controlled growth hormone study in HIV-positive patients (*www.clinicaltrials.gov NCT 00119769)
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Background

Today a 20-year-old HIV-positive patient can survive more than 43 years1 due to Highly Active Antiretroviral Therapy (HAART).2-5 However in the wake of HAART, a syndrome of metabolic and morphologic changes have emerged (HALS, fig. 1). Growth Hormone (GH) treatment of HALS has been investigated in HIV-positive patients, with positive clinical outcomes.6,7 Studies regarding lipodystrophy and long-term effects after growth hormone treatment are few. 9-month effect of GH on visceral adipose tissue, mid-thigh fat and fasting glucose, as well as a 6-month effect of the soft tissue in the face show beneficial effect of GH.8

Materials

39 HIV-positive patients with and without lipodystrophy included in the HIGH:low study, randomly recruited from an outpatient clinic serving 1400 patients.

Inclusion criteria:
HIV, male, age 21-60, Caucasian, weight-stable, HAART for 12 months.

Exclusion criteria:
Failure to complete the HIGH:low study.

Baseline characteristics:
Data from the last visit (week 86) of the HIGH:low study, randomly recruited from an outpatient clinic serving 1400 patients.

Endpoints:
- Primary: quality of life measured through the MOS-HIV questionnaire
- Secondary: fat distribution measured by DEXA scans and biochemistry (CD4, CD8 and HIV-RNA, glucose and insulin, lipids).

Aim

The study is a follow-up on an earlier performed study; the HIGH:low study, a placebo-controlled, randomised, double-blind study, evaluating the effects of low-dose growth hormone on metabolic, immunologic and morphologic parameters in HIV-positive patients.

The aim of the follow-up study is to evaluate the long-term effects of low-dose growth hormone. Based on the above mentioned studies we expect to see a gradual returning to the baseline values, especially for the psychological outcomes, whereas metabolic effects might be sustained for a longer period.

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