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Correlation of cardiac function indices and peripheral muscle mitochondrial changes in patients with severe adult growth hormone deficiency following growth hormone therapy

Submission date
10/02/2009

Recruitment status
No longer recruiting

Registration date
16/02/2009

Overall study status
Completed

Last Edited
27/06/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LREC/02/01/027

Study information

Scientific Title
Correlation of cardiac function indices and peripheral muscle mitochondrial changes in patients with severe adult growth hormone deficiency following growth hormone therapy: a single centre, randomised, double-blind placebo-controlled cross-over study over a six-month period followed by an open-label six-month phase

Acronym
CAMPING study

Study objectives
Patients with severe adult growth hormone deficiency have a twofold increase in cardiovascular death. Tentative evidence suggests that growth hormone therapy has cardiovascular benefits and there are reports of apparent cardiomyopathy being reversible with growth hormone administration. Attempts have been made at using growth hormone as specific therapy in heart failure with variable effects on left ventricular mass, left ventricular size and wall stress. However, there seems to be a consistent improvement in quality of life and increased exercise capacity. Others have assessed growth hormone replacement in adults and suggested there is an improvement in echocardiographic variables.

Studies reporting the effect of physical training on patients with chronic heart failure have shown a significant change in mitochondrial function in those patients in the exercise group. In those studies, the mitochondrial changes were significantly related to changes in oxygen uptake and at the ventilatory threshold. It is proposed that growth hormone treatment may significantly improve mitochondrial function which correlate to cardiac indices, giving a mechanism by which growth hormone may exert a cardioprotective effect.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Yorkshire LREC, 17/06/2002, ref: LREC/02/01/027

Study design
Single-centre randomised double-blind placebo-controlled cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult growth hormone deficiency

Interventions
Cross-over phase:
1. Active phase: recombinant growth hormone (rGH, dose = 0.4 mg/day) for 3 months
2. Placebo: sterile diluent containing glycerol and m-cresol or vice versa for 3 months

Patients are then crossed over to receive the alternative treatment. Thereafter, patients continued GH therapy for a further 6 months at same dose.

Intervention Type
Biological/Vaccine

Primary outcome(s)
1. Modification of mitochondrial function in vitro: needle muscle biopsy for measurement of mitochondrial function
2. Modification of cardiovascular function:
2.1. Echocardiogram for wall thickness ejection fraction, fraction with shortening of stroke distance
2.2. Magnetic resonance imaging (MRI) for wall thickness, muscle mass, ventricular volumes and ejection fraction
2.3. Exercise testing, six minute walk, metabolic gas exchange to derive peak VO2 and the ventilatory response to exercise
2.4. Muscle strength

Measured at baseline, 3 months, 6 months, 9 months and 12 months.

Key secondary outcome(s))
1. Blood will be withdrawn for cardiovascular risk indices including:
1.1. Fasting sample for homocysteine, urate, low level C-reactive protein, triglycerides, low density lipoprotein (LDL), high density lipoprotein (HDL)
1.2. Plasminogen activator inhibitor-1 (PAI 1), fibrinogen, factor 7 and 12
1.3. Fasting insulin glucose to determine insulin resistance by the homeostasis model assessment (HOMA) method
1.4. Lipid peroxides
2. Insulin-like Growth Factor-1 (IGF1) levels
3. Percentage of body fat (using bioimpedance technique), waist-hip ratio, blood pressure, weight

Measured at baseline, 3 months, 6 months, 9 months and 12 months.

Completion date
01/01/2005

Eligibility

Key inclusion criteria
1. Male or female patients aged between 18 and 75 years of age
2. Proven severe adult growth hormone deficiency by standard criteria
3. Ability to self-administer growth hormone
4. Ability to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
17

Key exclusion criteria
1. Inability to self-administer growth hormone
2. Patients not wishing for their GP to be informed

Date of first enrolment
01/07/2003

Date of final enrolment
01/01/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hull York Medical School
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Industry

Funder Name
Eli Lilly (UK) - unrestricted grant

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/02/2018	27/06/2019	Yes	No