

Dehydroepiandrosterone (DHEA) replacement in patients with secondary adrenal insufficiency (hypopituitarism)

Submission date

30/09/2004

Recruitment status

No longer recruiting

Registration date

30/09/2004

Overall study status

Completed

Last Edited

25/03/2020

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N0158124149

Study information

Scientific Title

Dehydroepiandrosterone (DHEA) replacement in patients with secondary adrenal insufficiency (hypopituitarism)

Study objectives

To evaluate the benefits of dehydroepiandrosterone (DHEA) replacement in terms of improvement in quality of life as compared to placebo in patients with secondary adrenal insufficiency and to assess its influence on serum lipids, insulin resistance and endothelial function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Double-blind placebo-controlled crossover study with a prearranged randomisation schedule

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Adrenal insufficiency

Interventions

For the first 4 months each patient would receive either 50 mg of DHEA administered orally or a placebo tablet of identical appearance. Following a washout period of one month the form of therapy would be switched and would be continued for a further period of 4 months.

Allocation details would only be known to an independent statistician and would remain coded until the trial is completed. Patients would be asked to attend the metabolic unit following overnight fast at 0, 4, 5 and 9 months. Pre-menopausal patients would be assessed during the follicular phase of the menstrual cycle. Any side effects would be noted and weight, body mass index (BMI) and blood pressure (BP). Quality of Life (QoL) Questionnaires would be completed and blood samples would be collected for biochemical and hormonal assays and biochemical markers of endothelial function. Short insulin tolerance test would be used as a measure of peripheral insulin sensitivity. After an overnight fast - 0.1 unit/kg body weight of soluble insulin would be injected at 0 minute and blood glucose would be measured at 0, 3, 6, 9, 12 and 15 minutes. The rate of fall of blood glucose, which indicates the endogenous glucose disposal rate, would be calculated from the linear regression of all values between 3 and 15 minutes and the rate of fall in percent per minute would be taken as an index of insulin sensitivity. In addition, biophysical markers of endothelial function would be measured by high resolution ultrasonography and would include carotid intima-media thickness and flow mediated dilatation of the brachial artery. For the latter, flow and diameter of the right brachial artery would be initially measured at rest. A tourniquet would be applied on the forearm and inflated to 250 mm of Hg for 5 minutes and the above measurements on the brachial artery would be repeated following the release of the tourniquet. The change in the diameter would be expressed as a percentage of the baseline diameter. Mean baseline values for each parameter would be compared to the mean post treatment values for placebo and for DHEA arms of the treatment

and statistical significance would be assessed using the Student-t test or the Mann Whitney U test, depending on whether the variables are normally distributed or not. 5% level of significance would be used.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

dehydroepiandrosterone (DHEA)

Primary outcome(s)

1. Body mass index
2. Blood pressure (BP)
3. Quality of life (QoL) assessment
4. Hormone, Biochemical and Endothelial markers (detail give above)
5. Insulin tolerance test
6. Ultrasonographic assessment of endothelial function by checking carotid intima-media thickness
7. Flow mediated dilatation of the brachial artery

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/10/2003

Eligibility**Key inclusion criteria**

1. 20 patients between the age of 20 and 60 years
2. With adrenal insufficiency secondary to panhypopituitarism of varying aetiology
3. Of at least one years duration enrolled from outpatient clinics of City General Hospital
4. They would be adequately replaced with regards to corticosteroid, thyroxine and sex steroid deficiency with unchanged replacement dose over the preceding 3 months
5. None of the patients would receive growth hormone replacement therapy
6. Patients with significant co-morbidity, those with hormone dependent conditions like breast cancer, pregnant women are excluded
7. Written consent would be obtained from all patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/12/2002

Date of final enrolment

01/10/2003

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

North Staffs Hospital Trust

Stoke-on-Trent

United Kingdom

ST4 6QG

Sponsor information**Organisation**

Department of Health

Funder(s)**Funder type**

Government

Funder Name

North Staffordshire Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration