ISRCTN14203656 https://doi.org/10.1186/ISRCTN14203656

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

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/03/2020	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0158124149

Study information

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

Study hypothesis
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

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

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

Condition
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 percept 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 disrupted 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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2002

Overall study end date
01/10/2003

Eligibility

Participant 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

Age group
Adult

Sex
Both

Target number of participants
20

Participant exclusion criteria
Not provided at time of registration

Recruitment start date
01/12/2002

Recruitment end date
01/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Staffs Hospital Trust
Stoke-on-Trent
United Kingdom
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Sponsor information

Organisation

Department of Health

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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Staffordshire Research and Development Consortium (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration