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A randomised, double blind, placebo-controlled study of the effects of Dehydroepiandrosterone (DHEA) replacement on vascular function in patients with primary and secondary adrenal insufficiency

Submission date
01/03/2005

Recruitment status
No longer recruiting

Registration date
10/06/2005

Overall study status
Completed

Last Edited
24/07/2019

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
SPON CU 086

Study information

Scientific Title
A randomised, double blind, placebo-controlled study of the effects of Dehydroepiandrosterone (DHEA) replacement on vascular function in patients with primary and secondary adrenal insufficiency

Study objectives
Patients with adrenal failure have impaired blood vessel function and that this can be improved by supplementing Dehydroepiandrosterone (DHEA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary and secondary adrenal insufficiency

Interventions
Interventions: DHEA replacement versus placebo
Patients with primary and secondary adrenal insufficiency will be randomly allocated into tratment and placeco groups. An initial assessment will be made of blood vessel function (pulse wave analysis, pulse wave velocity and endothelial fuction). Participants will commence on either treatment or placebo for 12 weeks followed by futher blood vessel funtion assessment. There will then be a 6 week wash out period followed by a 3rd blood vessel assessment then a futher cross-over treatment/placebo phase in which those who received the placebo in the first 3 months will now be given the active treatment and those who initially had the active treatment will be given the placebo. After another 3 months the trial will finish with a final assessment of blood vessel function.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dehydroepiandrosterone (DHEA)

Primary outcome(s)

Pulse wave velocity
Pulse wave analysis
Endothelial function
Blood tests for DHEA, high sensitivity C-reactive protein, plasminogen activator inhibitor-1, full lipid profile, testosterone, sex hormone binding globulin, oestradiol (males only), follicle stimulating hormone, luteinising hormone and liver function

Key secondary outcome(s)
Not provided at time of registration

Completion date
09/01/2008

Eligibility

Key inclusion criteria
Individuals with at least a 4 year history of primary adrenal insufficiency and those with secondary adrenal insufficiency as a result of pituitary surgery for a non-functioning pituitary tumour who did not receive radiotherapy and who are on stable doses of full hormone replacement including growth hormone.

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
01/05/2005

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of Endocrinology
Cardiff
United Kingdom
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Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Not defined

Funder Name
Funding is currently being sought from grant applications including the Cardiff and Vale NHS Small grants scheme and fellowship support from the Ipsen fund and the Royal College of Physicians

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	01/06/2009		Yes	No