

# 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

☐ Prospectively registered

☐ Protocol

**Registration date**

10/06/2005

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

24/07/2019

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Dafydd Aled Rees

**Contact details**

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University Hospital of Wales  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 treatment and placebo groups. An initial assessment will be made of blood vessel function (pulse wave analysis, pulse wave velocity and endothelial function). Participants will commence on either treatment or placebo for 12 weeks followed by further blood vessel function assessment. There will then be a 6 week wash out period followed by a 3rd blood vessel assessment then a further 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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/05/2005

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40

**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

CF14 4XW

## **Sponsor information**

**Organisation**

Cardiff University (UK)

**Sponsor details**

Chris Shaw

Cardiff University

Research and Commercial division

30-36 Newport Road

Cardiff

Wales

United Kingdom

CF23 0DE

**Sponsor type**

University/education

**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

## 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2009		Yes	No