

# Immune effects of dehydroepiandrosterone (DHEA) in adrenal insufficiency (IDHEAL)

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/08/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**  
N0265126494

## Study information

**Scientific Title**  
Immune effects of dehydroepiandrosterone (DHEA) in adrenal insufficiency (IDHEAL)

**Study objectives**  
The central hypothesis to be tested is that the pathologic DHEA deficiency that invariably accompanies adrenal insufficiency is the primary factor responsible for previously observed

impairment of immune function in these patients. Arising from this hypothesis the study aims to answer two questions:

1. Will immune function in patients with adrenal insufficiency show beneficial changes following DHEA replacement therapy?
2. Will DHEA replacement therapy alter endocrine-immune interactions as exemplified by steroidogenesis in immune cells?

### **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**

Nutritional, Metabolic, Endocrine: Adrenal insufficiency

### **Interventions**

25 patients with Addison's disease and 25 patients with hypopituitarism including secondary adrenal insufficiency will receive daily treatment with either 50 mg of DHEA or placebo orally for 16 weeks. At baseline and at the end of the treatment period patients will provide blood samples for analysis of T cell and neutrophil function, serum steroid hormones and steroid conversion in peripheral blood mononuclear cells. During the course of the study patients will undergo routine safety checks including clinical assessment and measurement of steroid hormone levels in monthly to bimonthly intervals.

The procedures described will be done for research purposes and are not normal clinical practice.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Dehydroepiandrosterone (DHEA)

### **Primary outcome(s)**

Not provided at time of registration

### **Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

17/07/2008

## Eligibility

**Key inclusion criteria**

25 patients with primary adrenal insufficiency and 25 patients with hypopituitarism including secondary adrenal insufficiency will be recruited from the Endocrine Clinics at the Queen Elizabeth Hospital and at the Selly Oak hospital. Patients will be on stable hormone replacement therapy including glucocorticoids and will have confirmed serum DHEAS levels below the lower limit of the sex-specific reference range. Age will be between 18 and 50 years.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

17/07/2003

**Date of final enrolment**

17/07/2008

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

University of Birmingham

Birmingham

United Kingdom

B15 2TT

# Sponsor information

## Organisation

Department of Health

## Funder(s)

### Funder type

Government

### Funder Name

University Hospital Birmingham NHS Trust (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration