

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

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/08/2015	Condition category 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

Study design

Randomised controlled trial

Primary study design

Interventional

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