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

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
17/08/2015	Nutritional, Metabolic, Endocrine	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
17/07/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

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
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (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