ISRCTN93511659 https://doi.org/10.1186/ISRCTN93511659

Glucocorticoid replacement therapy and fibrinolysis.

Submission date	Recruitment status
30/09/2005	No longer recruiting
Registration date	**Overall study status**
30/09/2005	Completed
Last Edited	**Condition category**
31/08/2010	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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0050153132

Study information

Scientific Title

Study objectives
To determine whether the dose of adrenal steroid replacement therapy in patients with pituitary disease, influences the fibrinolytic system (clot breakdown system) and determine whether patients who receive higher adrenal steroid replacement dose are at greater risk of cardiovascular disease.

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
Nutritional, Metabolic, Endocrine: Hypopituitarism

Interventions
The study will be of randomised, open-label, crossover design, comparing the effects of traditional glucocorticoid replacement regimens versus modern regimens on fibrinolytic parameters in patients with hypopituitarism.
Patients will have a two week period of treatment with either their current 'optimised' treatment regimen or with a higher dose (approx 30 - 50%) traditional type regimen. At the end of each two week period they will be admitted to a day case ward for hourly blood sampling over a 10 hour period. Blood will be taken for cortisol levels (adrenal steroid) in a standard fashion (a cortisol day profile) and for fibrinolytic parameters (i.e twice in total).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Fibrinolytic parameter measurements.

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/11/2004

Completion date
01/04/2007

Eligibility

Key inclusion criteria
All patients over 18 years with documented adult hypopituitarism with proven ACTH deficiency, currently under follow up in the Bradford Teaching Hospitals NHS Trust, who have provided informed consent will be potentially eligible to participate in the study. Patients will be recruited from either direct contact in OPD or via direct phone contact with an endocrine specialist nurse.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
15 patients and 10 controls will be recruited for the study.

Key exclusion criteria
1. Subjects requiring systematic steroid therapy
2. Subjects taking HRT or oral contraceptive
3. Subjects who are currently pregnant or who had recent pregnancy or abortion
4. Subjects with known malignancy
5. Subjects with known coagulopathy
6. Subjects who are currently taking or have recently taken anticoagulant therapy

Date of first enrolment
19/11/2004

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Diabetes & Endocrinology
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name

Bradford Teaching Hospitals NHS Foundation Trust (UK) Own account but no NHS R&D Support Funding

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?
Abstract results	results presented at Society for Endocrinology BES	06/11/2010		No	No