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
Dr Steve Peacey

Contact details
Diabetes & Endocrinology
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ
+44 (0)1274 382019
srpeacey@talk21.com

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Fibrinolytic parameter measurements.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

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

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