

# Glucocorticoid replacement therapy and fibrinolysis.

**Submission date**

30/09/2005

**Recruitment status**

No longer recruiting

**Registration date**

30/09/2005

**Overall study status**

Completed

**Last Edited**

31/08/2010

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ 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? |
|----------------------------------|--|--------------|------------|----------------|-----------------|
| <a href="#">Abstract results</a> | results presented at Society for Endocrinology BES | 06/11/2010   |            | No             | No              |