

# Consequences of suboptimal glucocorticoid replacement therapy in Addison's disease; The metabolic syndrome and QoL.

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1. Dutch patients with Addison's disease treated with suboptimal glucocorticoid replacement therapy have a reduced QoL; 2. Prevalence of the metabolic syndrome is higher among patients with Addison's disease treated with suboptimal...

|                             |                                                     |
|-----------------------------|-----------------------------------------------------|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving nog niet gestart                            |
| <b>Type aandoening</b>      | -                                                   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON22793

### Bron

NTR

### Aandoening

Addison's disease, metabolic syndrome, quality of life, glucocorticoid receptor polymorphisms

### Ondersteuning

**Primaire sponsor:** University Medical Center Utrecht

**Overige ondersteuning:** self-financing research

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

1. Presence of metabolic syndrome (3 or more abnormalities of waist circumference, blood

pressure, triglycerides, HDL-cholesterol, glucose);<br>

2. Quality of life score.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Introduction:

Patients with Addison's disease are treated with glucocorticoid replacement therapy (GRT). In spite of replacement therapy, patients with Addison's disease experience a lot of complaints. Glucocorticoids are essential for life but in excess they produce many unwanted effects on metabolism, cardiovascular, musculoskeletal and immune function. Glucocorticoid side effects are probably dose dependent. The serious adverse effects of high dose GRT are reported in large trials in patients with different diseases including, asthma, SLE and rheumatoid arthritis. The evidence on which to support clear recommendations about toxicity of low dose glucocorticoids is weak. Patients with Addison's disease are treated with long term low dose GRT. The effects of low dose GRT on quality of life and metabolism in this patient group are not clear.

Objective:

Assess the prevalence of the metabolic syndrome and quality of life in patients with Addison's disease treated with low dose GRT.

Study design:

Case-control observational study.

Study population:

Patients with primary adrenal insufficiency on a stable replacement therapy with glucocorticoids will be included in this study and results will be compared to data of age and sex matched controls.

Endpoints:

Quality of life and prevalence of the metabolic syndrome.

Inconvenience, risks and advantages:

Blood samples will be obtained and participants have to complete questionnaires. There is a small risk of infection or haematoma formation when obtaining the blood sample. An advantage of participating in this study is treatment of risk factors if the metabolic syndrome is diagnosed.

### **Doel van het onderzoek**

1. Dutch patients with Addison's disease treated with suboptimal glucocorticoid replacement therapy have a reduced QoL;
2. Prevalence of the metabolic syndrome is higher among patients with Addison's disease treated with suboptimal glucocorticoid replacement therapy compared to healthy controls.

### **Onderzoeksopzet**

Cross sectional.

### **Onderzoeksproduct en/of interventie**

1. Questionnaires;
2. Measurement of blood pressure, weight, height, waist circumference;
3. A fasting blood sample.

## **Contactpersonen**

### **Publiek**

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## Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with primary adrenal insufficiency in the age of 18-70 years.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Intercurrent infectious or serious disease;
2. Use of other oral medications containing glucocorticoids;
3. High dose inhalation glucocorticoids (>800 microgram a day);
4. Pregnancy.

## Onderzoeksopzet

### Opzet

|                  |                                                     |
|------------------|-----------------------------------------------------|
| Type:            | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel                                            |
| Toewijzing:      | N.v.t. / één studie arm                             |
| <b>Controle:</b> | N.v.t. / onbekend                                   |

## Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-01-2010               |
| Aantal proefpersonen:   | 120                      |
| Type:                   | Verwachte startdatum     |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 22-10-2009       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register       | ID                                  |
|----------------|-------------------------------------|
| NTR-new        | NL1945                              |
| NTR-old        | NTR2062                             |
| Ander register | CCMO : ABR-30390                    |
| ISRCTN         | ISRCTN wordt niet meer aangevraagd. |

## Resultaten

### Samenvatting resultaten

N/A