Consequences of suboptimal glucocorticoid replacement therapy in Addison*s disease; The metabolic syndrome and quality of life.

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Assess the prevalence of the metabolic syndrome and quality of life in patients with Addison*s disease treated with low dose GRT. Study the relation between GRT, QoL and glucocorticoid receptor polymorphisms

Ethical review	Not approved
Status	Will not start
Health condition type	Adrenal gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON32767

Source
ToetsingOnline

Brief title
Consequences of suboptimal GRTin Addison*s disease

Condition

- Adrenal gland disorders
- Lipid metabolism disorders

Synonym
Addison's disease, primary adrenal insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Het onderzoek wordt gefinancieerd door derde en vierde geldstroom. De DIGD beheert op meerdere kostenplaatsen (door ons "kostenplaats endocrinologie" genoemd) het resterend saldo van eerder uitgevoerde onderzoeksprojectenvan de afdeling endocrinologie. Dit resterend saldo wordt o.a. voor dit onderzoek aangewend.

Intervention

Keyword: Addison's disease, glucocorticoid replacement therapy, metabolic syndrome, quality of life

Outcome measures

Primary outcome

1) Presence of metabolic syndrome (3 or more abnormalities of waist

circumference, blood pressure, triglycerides, HDL

cholesterol, glucose)

2) Quality of life score

Secondary outcome

Presence of glucocorticoid receptor polymorfisms and GRT in relation to the

metabolic syndrome and QoL.

Study description

Background summary

Patients with Addison*s disease are treated with glucocorticoid replacement therapy (GRT). However, many patients still experience complaints. This is probably due to our inability to exactly mimic the hypothalamic-pituitary diurnal rhythm, frequently leading to under- or overtreatment. In excess, glucocorticoids produce many unwanted effects on metabolism and the cardiovascular system. The unwanted adverse effects of treatment with high dose glucocorticoids are reported in large trials. Patients with Addison*s disease are treated with long term low dose GRT. The evidence on which to support clear

recommendations about toxicity of low dose glucocorticoids is weak.
Difficulties in optimizing GRT could also be caused by glucocorticoid receptor polymorphisms, because they lead to a variable response to glucocorticoids. The effects of GRT and glucocorticoïd receptor polymorphisms on quality of life and metabolism in patients with Addison*s disease are not clear.

Study objective

Assess the prevalence of the metabolic syndrome and quality of life in patients with Addison*s disease treated with low dose GRT. Study the relation between GRT, QoL and glucocorticoid receptor polymorphisms

Study design

Case-control observational study

Study burden and risks

Indexgroup:
Disadvantages of the study are the burden of height, weight, waist circumference and blood pressure measurement, collection of blood and completing the questionnaires concerning aspects of the replacement therapy and quality of life. There is a small risk of infection or haematoma formation in obtaining a blood sample.
An advantage of participating in this study is treatment of risk factors if the metabolic syndrome is diagnosed.

Controlgroup:
Disadvantage of the study is the burden of completing questionnaires concerning aspects of quality of life

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- primary adrenal insufficiency
- 18-70 years
- stable glucocorticoid replacement therapy (no adjustments of regime and dosage for 3 months)

Exclusion criteria

- intercurrent infectious or serious disease for which it is necessary to increase glucocorticoid dosage
- high dose inhalation glucocorticoids (>800 microgram a day)
- pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	242
Type:	Anticipated

Ethics review

Not approved

Date:	03-02-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	2062 (Nederlands trial register)
CCMO	NL30390.041.09