Study on the effect of prednisolone on muscle strength and mobility

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24482

Source
NTR

Brief title
PGC-study

Health condition

ANCA associated vasculitis, Steroid myopathy, Glucocorticoid toxicity

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: University Medical Center Groningen (UMCG)

Intervention

Outcome measures

Primary outcome

-Strength of knee extension and hip flexion (N), measured by handheld dynamometer

-Mobility (average kcounts/day), measured by accelerometer

-Physical summary score of RAND-36

Secondary outcome

These include anthropometric measures, strenght of elbow flexors, bioelectric impedance analysis, five-times sit-to-stand transfer and mobility questionnaires

Study description

Background summary

Glucocorticoids (GCs) are part of standard treatment in all AAV patients, regardless of induction and maintenance therapy. Unfortunately, GCs are associated with many short-term and long-term adverse effects. Patients in our center often report a decrease in leg muscle strength, resulting in difficulties standing up from a chair and walking up stairs. In this study, we aim to prospectively monitor the toxic effects of glucocorticoids in AAV patients treated for active disease. In particular, we will explore the effects on muscle strength, mobility and physical health status. These measurements could then be used for monitoring future interventions aimed at improving mobility of patients receiving glucocorticoid treatment.

Study objective

-Patients experience decrease in muscle strength, mobility and physical health status during treatment with high-dose glucocorticoids for ANCA associated vasculitis

-The difference is clinically relevant, and some or all patients may require training exercises

Study design

T1=informed consent date, T2=4 weeks after start of treatment, T3=8 weeks after start of treatment, T4=12 weeks after start of treatment, T5=6 months after start of treatment

-Length will be measured at T1.

-SF-36 and Accelerometer measurements will be done at T1, T3 and T5

-All other measurements will be performed at all time points.

Intervention

No interventions. Only additionional non-invasive measurements will be performed

Contacts

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Eligibility criteria

Inclusion criteria

Patients with new onset or relapse of Granulomatosis with Polyangiitis or Microscopic Polyangiitis, who have an indication of induction treatment with cyclophosphamide (or other immunosuppressive) and prednisolone (1mg/kg/day, dosage according to treatment protocol)

Exclusion criteria

Patients <18 years

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-06-2015
Application type:	First submission

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
NTR-new	NL5084
NTR-old	NTR5216
Other	UMCG Research Register : 201500280

Study results