Study on the effect of prednisolone on muscle strength and mobility

Gepubliceerd: 18-06-2015 Laatst bijgewerkt: 18-08-2022

-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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24482

Bron
NTR

Verkorte titel
PGC-study

Aandoening

ANCA associated vasculitis, Steroid myopathy, Glucocorticoid toxicity

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: University Medical Center Groningen (UMCG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

-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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

-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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients <18 years

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-06-2015
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	NL5084
NTR-old	NTR5216

Register	ID
Ander register	UMCG Research Register : 201500280

Resultaten