Effect of Supplemental Hydrocortisone During Stress in Prednisolone-induced Adrenal Insufficiency

NCT05435781

Status	RECRUITING
Phase	Phase 4
Sponsor	Marianne Christina Klose
Enrollment	250 participants

Key Eligibility Criteria

Inclusion (5)

- Age e 50 years
- Women must be postmenopausal (FSH is measured at the screening visit)
- A diagnosis of PMR/GCA, or both conditions combined.
- Treatment with prednisolone e12 weeks
- Ongoing prednisolone treatment, with current daily prednisolone dose \> 0 mg and d5 mg. The dose must have been d5 mg for minimum 2 weeks at the time of the screening visit.

Exclusion (8)

- Known primary or secondary adrenal insufficiency
- Known Cushing's Syndrome
- Known allergy towards study medication ingredients
- Severe comorbidity: Heart failure (New York Heart Association class IV); Kidney failure with an estimated glomerular filtration rate \<30 mL/min (Chronic kidney disease stage 4-5); Liver disease in the form of cirrhosis; Active cancer; Known severe immune deficiency; A history of psychiatric disease requiring treatment by a psychiatric department (for affective disorders only if within the last year before study entry)
- Alcohol consumption \>21 units per week

... and 3 more (see full listing online)

Locations (3 total)

Department of Endocrinology, Aarhus University Hospital, Aarhus, Denmark
Department of Medical Endocrinology, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark
Department of Endocrinology, Odense University Hospital, Odense, Denmark