Phase 2 Chronocort Study Results

Current glucocorticoid medications available to treat CAH are suboptimal as they cannot replace cortisol in a circadian manner. We are very excited to report findings from a recent Phase 2 study using Chronocort® (Diurnal Limited, UK), a modified-release capsule formulation of hydrocortisone (ClinicalTrials.gov Identifier: NCT01735617). The study was conducted at the National Institutes of Health Clinical Center, Bethesda, Maryland under Dr. Deborah Merke. The study began in December 2012 and was completed in December 2013. 16 adults with classic CAH participated in this 6 month study. Thirteen patients were recruited through the NIH Natural History Study of Excess Androgen (ClinicalTrials.gov Identifier: NCT00250159) and three patients were recruited through a CARES advertisement. The study had 4 inpatients visits to the NIH Clinical Center. All patients were started on the same Chronocort® dose (10mg in the morning and 20mg at night) and dose adjustments were made based on detailed hormone measurements and patient symptoms. During the study, dose reductions were done in half of the patients. In this study, Chronocort® therapy in CAH patients resulted in cortisol hormone levels in the blood over 24 hours similar to physiologic cortisol levels seen in healthy individuals without CAH. On Chronocort® therapy, patients experienced a significant decrease in androgen levels (17-hydroxy progesterone and androstenedione) throughout the day. All patients completed the study and no serious adverse effects occurred. Results from this Phase 2 study were recently presented by Dr. Deborah Merke at the Annual Endocrine Society meeting, San Diego, California, March 2015 and the Canadian Pediatric Endocrine Group Scientific Meeting, Halifax, Canada, February 2015. The published manuscript is available on PubMed.gov (Mallappa A et al PubMed ID: 25494662). With these exciting results, planning is underway for a large multi-center clinical trial, the next phase of the study of Chronocort® therapy.