

INCLUSION CRITERIA

1. Known congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency (classic CAH) diagnosed in childhood with documented (at any time) elevated 17-hydroxyprogesterone (17-OHP) and/or androstenedione (A4) and currently treated with hydrocortisone, prednisone, prednisolone or dexamethasone (or a combination of the aforementioned glucocorticoids).
2. Aged 18 and above.
3. Provision of signed written informed consent.
4. If female: non-pregnant and non-lactating who are post-menopausal, naturally or surgically sterile, or of childbearing potential with a negative urinary pregnancy test and using medically acceptable method of contraception.
5. Plasma renin activity (PRA) less than 2 times the upper limit of normal (ULN) at screening or within 3 months prior to screening, except in subjects who have been diagnosed with hypertension where the renin is not being used to monitor fludrocortisone replacement.

EXCLUSION CRITERIA

1. Co-morbid condition requiring daily administration of a medication (or consumption of any material) that interferes with the metabolism of glucocorticoids.
2. Clinical or biochemical evidence of hepatic or renal disease. Creatinine over twice the ULN or elevated liver function tests (ALT or AST >2 times the ULN).
3. Subjects on regular daily inhaled, topical, nasal or oral steroids for any indication other than CAH.
4. Subjects with any other significant medical or psychiatric conditions that in the opinion of the investigator would preclude participation in the trial.
5. History of malignancy (other than basal cell carcinoma successfully treated >24 weeks prior to entry into the study).
6. Participation in another clinical trial of an investigational or licensed drug or device within the 12 weeks prior to screening.
7. Subjects with a history of bilateral adrenalectomy.
8. Subjects having previously been exposed to Chronocort®.
9. Subjects unable to comply with the requirements of the protocol.

