

# Pharmacokinetic (PK), Pharmacodynamic (PD) and Tolerability of Osilodrostat in Pediatric Patients With Cushing's Syndrome

NCT03708900

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Status	RECRUITING
Phase	Phase 2
Sponsor	RECORDATI GROUP
Enrollment	12 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Male and female children and adolescents from 2 to < 18 years of age with Cushing's syndrome of endogenous origin: Who have failed surgery (or) who are awaiting surgery (or) for whom surgery is not an immediate option. For patients who are awaiting surgery, the study treatment could be less than 12 weeks.
- Patients must weigh > 10 kg.
- The diagnosis of Cushing's syndrome must be confirmed by each of the following:
  - a) The clinical criterion of decreasing growth percentiles with increasing weight (as evidenced by the presence of a contrast in height and BMI SD scores, for example a SDS < 0 and BMI SDS > 0, or a strong clinical suspicion of Cushing's syndrome, such as photographic evidence of a change in facial appearance); 3b) Abnormal low-dose (0.5 mg Q6h x 48 hours, or overnight 15mcg/kg [max 1 mg]) dexamethasone suppression test, defined as plasma cortisol levels > 1.8 mcg/dl, at time point 48 hours (0.5 mg Q6h x 48 hours) or 9 to 12 hours (overnight 15mcg/kg [max 1 mg]) after the first dose of dexamethasone; (OR) Midnight serum cortisol levels > ULN, assessed while the patient is sleeping and after pre-cannulation (OR) two samples of late-night salivary cortisol greater than ULN for the assay. 3c) Two 24-hour urinary free cortisol values > 1.3 x ULN;
  - \. Able to swallow study drug tablets (not crushed or split) or the content of the capsules mixed with water.

... and 1 more (see full listing online)

### Exclusion (21)

- Patients with macroadenoma complicated by compressive symptoms (requiring urgent surgical intervention) or at high risk for compressive symptoms due to mass effect of tumor (concern of corticotroph tumor progression).
- Insufficient washout period from any other medication used to lower cortisol levels (5 half-lives of any drug).
- Use of other investigational drugs at the time of enrollment, or within 30 days, or prior to completion of a wash-out duration that is at least 5 half- lives of the drug, at the time of enrollment, whichever is longer. Local regulations may require a longer wash-out period or specify other limitations for participation in an investigational trial, in which case they will be applicable as well.
- History of hypersensitivity to drugs of the same or similar chemical classes as osilodrostat.
- History of malignancy of any organ system (other than localized basal cell carcinoma of the skin), treated or untreated, within the past 5 years, regardless of whether there is evidence of local recurrence or metastases.

... and 16 more (see full listing online)

## Locations (15 total)

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University of California San Francisco UCSF, San Francisco, California, United States  
ABMED Clinical Research Corp, Cape Coral, Florida, United States  
Ann & Robert H. Lurie Children's Hospital, Chicago, Illinois, United States  
... and 12 more locations

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<https://clinicaltrials.gov/study/NCT03708900>

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