CATALYST

Study of Hypercortisolism in Patients with Difficult-to-Control Type 2 Diabetes

IN PATIENTS WITH DIFFICULT-TO-CONTROL TYPE 2 DIABETES (T2D),

THE PREVALENCE OF ENDOGENOUS HYPERCORTISOLISM IS SIGNIFICANTLY HIGHER THAN PREVIOUSLY THOUGHT[1-4]

CATALYST is the largest US prospective clinical trial ever conducted to investigate the prevalence of endogenous hypercortisolism in patients with difficult-to-control T2D.[5]*

PRIMARY ENDPOINT: Prevalence of endogenous hypercortisolism, defined as[5]:

- 1-mg dexamethasone suppression test (DST) with a cutoff of >1.8 µg/dL[5]
  - Recommended by the Endocrine Society Guidelines[6]
  - An inexpensive, accessible, and relatively easy-to-administer test (requires 1 tablet in the evening and 1 blood draw in the morning)[7]
- Dexamethasone levels ≥140 ng/dL[5]

KEY EXPLORATORY ENDPOINTS: Percentage of patients with/without adrenal adenomas[5]

CATALYST PATIENT SELECTION

INCLUSION CRITERIA

Patients with difficult-to-control T2D.[5]* Published research suggests that patients who meet this criteria have a higher risk of having endogenous hypercortisolism.[8,9]

PARTIAL EXCLUSION CRITERIA[5]

Patients with recognized causes of misleading 1-mg DST results, including:

- Taking oral estrogen within 3 weeks of testing
- Alcoholism
- Acute illness/injury
- Psychosis
- Night shift worker
- Untreated sleep apnea

1055 PATIENTS WERE EVALUATED WITH A 1-MG DST[4]

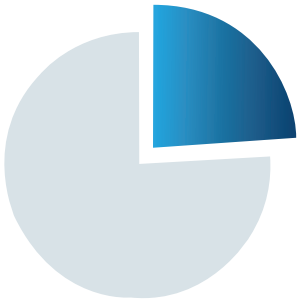
Patients with a DST >1.8 ug/dL with serum dexamethasone ≥140 ng/dL were considered positive for endogenous hypercortisolism.[5]

Nearly 1 in 4 patients (n=253)
had endogenous hypercortisolism[4]

*Patients with an HbA1c level ≥7.5% and ≤11.5%. Patients were also taking 3 or more T2D medications, insulin and other T2D medication(s), 2 or more T2D medications with the presence of ≥1 microvascular or macrovascular complications, and 2 or more T2D medications and 2 or more hypertension medications.[5]

PHASE 1 CATALYST STUDY RESULTS

24% OF PATIENTS WITH DIFFICULT-TO-CONTROL T2D HAD ENDOGENOUS HYPERCORTISOLISM[4]



PREVALENCE OF ENDOGENOUS HYPERCORTISOLISM IN PATIENTS WITH DIFFICULT-TO-CONTROL T2D WHO MET THE INCLUSION AND EXCLUSION CRITERIA[4]

24%
(253/1055)

Endogenous hypercortisolism was defined as:

- 1-mg DST >1.8 µg/dL
- Confirmed dexamethasone levels ≥140 ng/dL

203 patients who had a DST >1.8 µg/dL were evaluated with abdominal CT scan. 34% (69/203) of patients were found to have an adrenal abnormality.[4]

23.2%	3.4%	3.9%	3.4%
had a unilateral adenoma	had a unilateral/ bilateral enlargement	had a bilateral adenoma	had other adrenal abnormality
(47/203)	(7/203)	(8/203)	(7/203)

*Based on n=203 abdominal CT scans available as of May 29, 2024, read locally at the study sites. Central readings by an expert adrenal radiologist is ongoing.

Screen for endogenous hypercortisolism in patients with difficult-to-control T2D with a 1-mg DST

Difficult-to-control T2D was defined as patients having an HbA1c of ≥7.5% and ≤11.5%, and taking[5]:

- 3 or more T2D medications
- Insulin and other T2D medication(s)
- 2 or more T2D medications with the presence of ≥1 microvascular or macrovascular complications
- 2 or more T2D medications and 2 or more hypertension medications

Stay in contact with your Corcept clinical specialist for more information about the CATALYST clinical trial.

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