

Online Resource 2

How are growth hormone and insulin-like growth factor-1 reported as markers for drug effectiveness in clinical acromegaly research? A comprehensive methodologic review

Pituitary

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Data extraction form – systemic review; An overview of study characteristics and method disclosure

Title	
Authors	
Year	
Trial identifier	
Study design	Prospective/retrospective/cohort/case-control/RCT
Study phase	Phase 1/2/3 – Post approval
Sample size	Total number of subjects that were included in the study
Compound	Compounds used in the study
Patient population	What population was studied
Response criteria	Biomarkers that were used to determine the effect: A) GH B) IGF-I C) OGTT
GH measurement	Sampling design that was used to measure GH. E.g. random 1-point GH measurement, 3-point mean with 30 minute interval.

GH measurement time point	Was the clock time, time after dose or fasting state of the subjects disclosed?
GH cut-off	GH concentration that was used to establish biochemical control
IGF-1 measurement	Sampling design that was used to measure IGF-1. E.g. 1 sample, 2 samples
IGF-1 measurement time point	Was the clock time, time after dose or fasting state disclosed?
IGF-1 cut-off	IGF-1 concentration that was used to establish biochemical control
OGTT method	If OGTT results were included, was the method for the OGTT reported? E.g. glucose dose, sampling frequency, cut-off for nadir.
PK	Was PK measured?
Number of PK samples per subject	Total blood samples taken from 1 individual
PK method	Method used to analyze the pharmacokinetic data
Statistics	Used summary statistics per biomarker. E.g. Mean (SD); Median (IQR); Median (Range); ULN corrected IGF-1? Yes/No
Assay used	Analytical assay used for GH and IGF-1 analysis, if reported.