

Study Identification

First Author:	Year:
Language:	Location:
Funding Source Specify: <input type="checkbox"/> Industry <input type="checkbox"/> Government/Foundation Academia <input type="checkbox"/> Other/Unknown	Citation:

Design Characteristics

Study Design
<input type="checkbox"/> RCT - Parallel <input type="checkbox"/> Obs - Registry
<input type="checkbox"/> RCT - Crossover <input type="checkbox"/> Case Report
<input type="checkbox"/> Obs - Cohort <input type="checkbox"/> Other
<input type="checkbox"/> Obs - Case Control
<input type="checkbox"/> Obs - Cross-Sectional

Study Population

Inclusion Criteria:		
Exclusion Criteria:		
rhGH product name:	Dose/Frequency as given in article:	Total dose/week:
Control product:	Dose/Frequency:	

Run-in period? <input type="checkbox"/> Yes <input type="checkbox"/> No	Describe Run-in:		Patients removed from run-in, why:	
#enrolled:	#completed:	#Withdrawals:	#rhGH w/d, why:	#Control w/d, why:
Length of Study:		Duration of follow-up:		

Baseline Characteristics

	rhGH group	Control group
N		
Age: mean (SD)*		
Males: number (%)		
Tanner Stage		
Height (cm): mean (SD)*		
Height Z-score		
Height percentile		
Weight (kg)		
Weight Z-score		
Weight percentile		
BMI (kg/m ²)		
BMI Z-score		
Lean Body Mass (kg)		
FVC (L)		

FVC % Predicted		
FEV ₁ (L)		
FEV ₁ % Predicted		

*If not reported as mean and SD, please specify

Concurrent Therapies

Nutrition:				
<input type="checkbox"/> Food				
<input type="checkbox"/> Enteral Nutrition				
<input type="checkbox"/> TPN				
	rhGH Group		Control Group	
	# Patients	Mean Dose (SD)*	# Patients	Mean Dose (SD)*
Pancreatic Enzymes				
Inhaled Tobramycin				
Recombinant Human DNase				
Inhaled Beta-2 Agonists				
Inhaled Anticholinergics				
Inhaled Corticosteroids				
Oral Corticosteroids				
IV Corticosteroids				
Oral NSAIDs				

*If not reported as mean and SD, please specify

Weight (kg)										
Weight velocity (kg/y)										
Weight Z-score										
Weight percentile										
BMI (kg/m ²)										
BMI Z-score										
%Ideal Body Weight										
Lean Body Mass (kg)										

*If not reported as mean and SD, please specify

Bone Outcomes (Continuous)—Means (Standard Deviations or Standard Errors; please specify)

	rhGH group				Control group					
Sample size (n)										
	Baseline Mean (SD)*	Endpoint Mean (SD)	Mean Change from Baseline (SD)	P-value for Change from Baseline	Baseline Mean (SD)	Endpoint Mean (SD)	Mean Change from Baseline (SD)	P-value for Change from Baseline	Mean Difference between groups (SD)	P-value for Difference Between Groups
Bone age (y)										
Bone mineral content (g)										
Bone mineral content Z-score										

*If not reported as mean and SD, please specify

HRQOL Sub-score 3 Please specify										
Antibiotic use—Definition of outcome:										
Antibiotic use										

*If not reported as mean and SD, please specify

	rhGH group	Control group
Sample size (n)		
Categorical outcomes below :		
Hospitalizations (number of events)		
Pulmonary Exacerbation—Definition of outcome:		
Pulmonary Exacerbations (number of events)		
Cancer—Describe type:		
Cancer (number of cases)		
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Cancer (number of cases)		
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Cancer (number of cases)		
Cancer—Describe type:		
Cancer (number of cases)		

Glucose Parameters—Means (Standard Deviations or Standard Errors; please specify)

	rhGH group				Control group					
Sample size (n)										
	Baseline Mean (SD)*	Endpoint Mean (SD)	Mean Change from	P-value for Change from	Baseline Mean (SD)	Endpoint Mean (SD)	Mean Change from	P-value for Change from	Mean Difference between	P-value for Difference Between

			Baseline (SD)	Baseline			Baseline (SD)	Baseline	groups (SD)	Groups
HbA1c (%)										
Random BG (mg/dl)										
Fasting BG (mg/dl)										
Stimulated BG (mg/dl)										
Postprandial BG (mg/dl)										
			rhGH group				Control group			
Sample size (n)										
Categorical outcomes below :										
Hyperglycemia (number of events)										
Onset of DM (number of events)										

*If not reported as mean and SD, please specify

Biomarkers (Continuous)—Means (Standard Deviations or Standard Errors; please specify)

	rhGH group				Control group					
Sample size (n)										
	Baseline Mean (SD)*	Endpoint Mean (SD)	Mean Change from Baseline (SD)	P-value for Change from Baseline	Baseline Mean (SD)	Endpoint Mean (SD)	Mean Change from Baseline (SD)	P-value for Change from Baseline	Mean Difference between groups (SD)	P-value for Difference Between Groups
IGF-I (ng/dl)										
IGF-I Z-score										
IGFBP-3 (ng/ml)										
IGFBP-3 Z-score										

*If not reported as mean and SD, please specify