

# Cardiovascular Risk Factors and Treatment Outcomes with Romosozumab in Patients with Severe Osteoporosis: A Multicenter Study in Castile and Leon

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## BACKGROUND

- Romosozumab is an IgG2 monoclonal antibody with high affinity and specificity for sclerostin. It is indicated for postmenopausal women with severe osteoporosis and high fracture risk. However, studies such as the ARCH trial have raised concerns about an increased incidence of severe cardiovascular events with romosozumab, leading to its contraindication in patients with pre-existing cardiovascular conditions.

## OBJECTIVES

- The primary aim of this study was to explore the real-world use of romosozumab among patients with severe osteoporosis in Castile and León. Specifically, the study sought to analyze the prevalence of cardiovascular risk factors, treatment histories, densitometric values, bone remodeling markers, and adverse effects associated with the treatment.

## METHODS

- A descriptive, cross-sectional, multicenter study was conducted across various healthcare centers in Castile and León. Data were collected from patients with severe osteoporosis treated with romosozumab. The analysis included sociodemographic characteristics, treatment history, baseline and post-treatment densitometric values, densitometric measures, analysis of bone remodeling markers, adverse effects and for the reasons for discontinuation of treatment.

## RESULTS

- Table 1 shows the different variables collected in the study. Notably, one of our patients experienced a cardiovascular event that led to the discontinuation of the drug, although they already had cardiovascular risk factors (diabetes, hypertension, age 83).
- Table 2 shows the improvement in densitometric values (illustrated in Figure 1), as well as the evolution of the CTX marker before and after treatment with romosozumab.

## CONCLUSION

Romosozumab is a highly effective treatment for severe osteoporosis, delivering significant improvements in bone density and remodeling markers, especially in the spine and hip. While its efficacy is well demonstrated, this study underscores the importance of individualized treatment planning, particularly for patients with cardiovascular comorbidities. The occurrence of a severe cardiovascular event in a high-risk patient highlights the need for thorough cardiovascular assessment before initiating therapy.

Variable	Value
<b>Sex</b>	
Male (n, %)	2 (2.5%)
Female (n, %)	79 (97.5%)
<b>Age (median ± SD)</b>	70 ± 9 years
<b>Age of Menopause (median ± SD)</b>	48 ± 5 years
<b>Cardiovascular Risk Factors (n, %)</b>	
Arterial hypertension	27 (33.33%)
Diabetes	3 (3.7%)
Dyslipidemia	27 (33.33%)
Obesity	8 (9.88%)
Underweight	4 (4.94%)
<b>Smoking History (n, %)</b>	
Current smokers	9 (11.11%)
Former smokers	9 (11.11%)
Never smokers	63 (77.78%)
<b>Previous Treatments (median ± SD)</b>	
Oral Bisphosphonates	1 ± 0.6
Intravenous Bisphosphonates	24 (29.63%)
Teriparatide	13 (16.05%)
Denosumab	16 (19.75%)
Raloxifene	3 (3.7%)
<b>History of Fractures (median ± SD)</b>	
Vertebral	168 (89.36%)
Rib	3 (1.6%)
Distal Radius	10 (5.32%)
Hip	7 (3.72%)
More than 1 fracture	50 (61.73%)
<b>Treatment Status (n, %)</b>	
Patients who completed treatment	37 (45.68%)
Patients still undergoing treatment	35 (43.21%)
Patients who discontinued treatment	9 (11.11%)
<b>Reasons for Treatment Discontinuation (n, %)</b>	
Death by cancer	1 (1.23%)
Inferior ST-elevation myocardial infarction (STEMI)	1 (1.23%)
Poor adherence	1 (1.23%)
Recurrent urinary tract infections	2 (2.46%)
Start of antitumor treatment	2 (2.46%)
Injection site reactions	2 (2.46%)

Table 1: Patient Characteristics and Treatment History

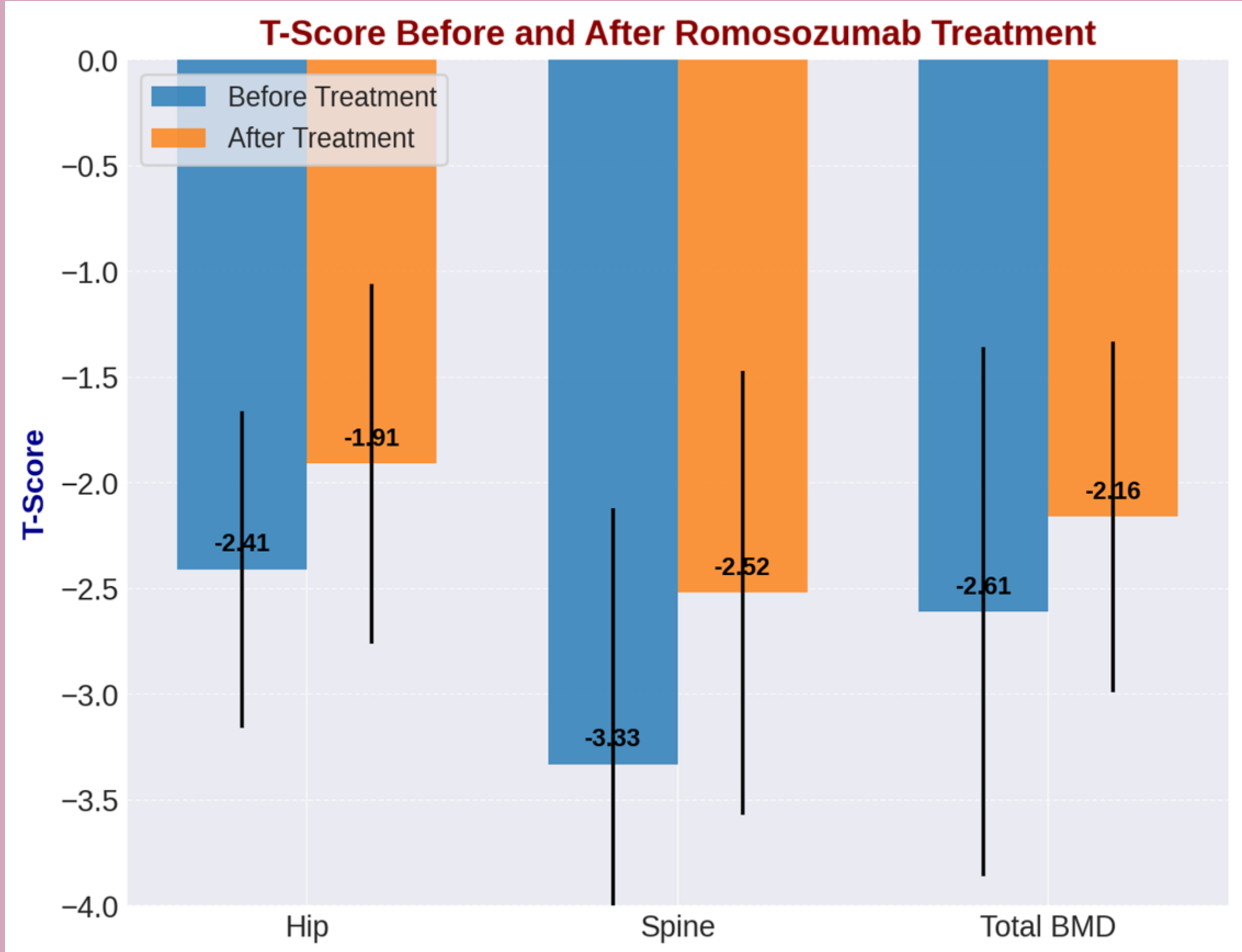


Figure 1: Evolution of T-Score Before and After Treatment with Romosozumab

Variable	Value
<b>Densitometry Measurements (median ± SD)</b>	
<b>Baseline</b>	
Hip T-Score	-2.41 ± 0.75
Vertebral T-Score	-3.33 ± 1.21
Total T-Score	-2.61 ± 1.25
<b>Post-Treatment</b>	
Hip T-Score	-1.91 ± 0.85
Vertebral T-Score	-2.52 ± 1.05
Total T-Score	-2.16 ± 0.83
<b>Bone Turnover Marker (median ± SD)</b>	
Baseline B-CrossLaps	0.54 ± 0.35
Post-Treatment B-CrossLaps	0.32 ± 0.34

Table 2: Densitometry and Bone Turnover Marker Measurements