PronoKal®
Rigour and science for weight loss

PROMESA I Study

Study Title
Study on the effectiveness and safety of the PronoKal® Method for controlled weight loss.

Main Objective
Evaluate the effectiveness and safety of the PronoKal® Method for controlled weight loss in non-institutionalised overweight or class I, II, III or IV obese patients (BMI≥ 30) between the ages of 16 and 65.

Secondary Objectives
Show an improvement in obesity-related health conditions due to controlled weight loss.

Study Design and Type
Retrospective, observational, multi-centre study.

Researching Doctors and Research Centres
200 research doctors from throughout Spain who were treating patients with overweight (BMI>25) or obesity (BMI>30) at their private practice participated in the study.

Study Population
Overweight and obese patients who followed a Protein Diet through the PronoKal® Method for controlled weight loss beginning in January 2007.

PRIMARY RESULTS

Sample Characteristics (1,892 patients)

Total patients N=1892	Groups	%	average ± SD
Sex	Male	35.20	-
	Female	64.80	-
Age	-	-	42.17 ± 11.41 years
Smoker	Yes	22.23	13.69 ± 9.33 cig/d
Sedentary Lifestyle	Yes	67.76	-
Comorbidities	Type 2 Diabetes	2.05	-
	AHT	11.79	-
	Dyslipidaemia	14.20	-
	Gout	1.51	-
	Cholelithiasis	1.03	-
Family History of Obesity	Yes	26.21	-
Weight	Male	-	98.66 ± 19.84
	Female	-	83.93 ± 14.35
BMI	Male	-	33.78 ± 7.09
	Female	-	32.11 ± 5.21
Who Obesity Classification	Overweight	36.26	-
	Obesity 1	36.63	-
	Obesity 2	17.86	-
	Obesity 3	9.25	-

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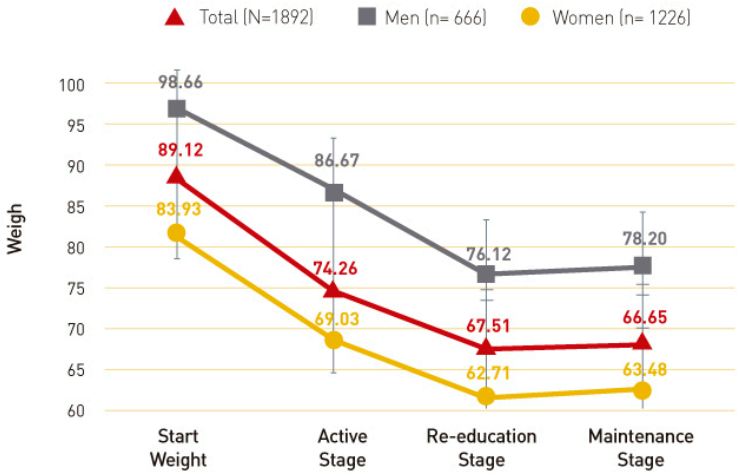
Data on the Effectiveness for Weight Loss

Stages	Weight (kg) avg±SD (n)		
	Total	Men	Women
Start Weight	89.12 ± 17.9 (n=1892)	98.66 ± 19.8 (n=666)	83.93 ± 14.4 (n=1226)
Stage 1 (Active)	74.26 ± 13.7 (n=641)	86.67 ± 14.0 (n=190)	69.03 ± 9.6 (n=451)
Stage 2 (Re-education)	67.51 ± 10.8 (n=361)	76.12 ± 11.4 (n=67)	62.71 ± 6.8 (n=294)
Stage 3 (Maintenance)	66.65 ± 10.9 (n=204)	78.20 ± 13.3 (n=44)	63.48 ± 7.5 (n=160)
Total weight lost (kg)	18.45 ± 10.7	19.90 ± 10.4	17.64 ± 10.4
p	< 0.05*	< 0.05*	< 0.05*

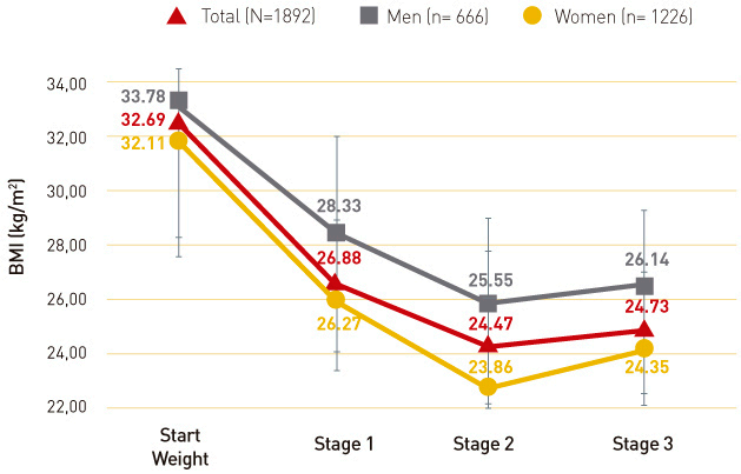
*Significant difference for start value/active/re-education stages. No significant difference between re-education and maintenance stages.



Data on the Effectiveness for BMI Reduction

Stages	BMI (kg/m²) avg±SD (n)		
	Total	Men	Women
Start Weight	32.69 ± 6.0 (n=1892)	33.78 ± 7.1 (n=666)	32.11 ± 5.2 (n=1226)
Stage 1 (Active)	26.88 ± 3.5 (n=641)	28.33 ± 3.5 (n=190)	26.27 ± 3.3 (n=451)
Stage 2 (Re-education)	24.47 ± 2.4 (n=361)	25.55 ± 2.3 (n=67)	23.86 ± 2.3 (n=294)
Stage 3 (Maintenance)	24.73 ± 2.7 (n=204)	26.14 ± 2.7 (n=44)	24.35 ± 2.5 (n=160)
Total BMI reduction (kg/m2)	7.96 ± 3.3	7.64 ± 4.4	7.76 ± 2.6
p	< 0.05*	< 0.05*	< 0.05*

*Significant difference for start value/active/re-education stages. No significant difference between re-education and maintenance stages.



Data on the Effectiveness for Improvement in Obesity-Related Health Conditions

Percentage of patients with alteration in analytical parameters					
Variable (mg/dl)	Baseline	Visit 1 (7-10 days)	Stage 1 (active)	Stage 2 (re-education)	p
Glucose	7.68	7.37	2.07	5.45	*
Uric acid	9.92	13.33	2.90	9.09	*
Cholesterol	16.19	-	3.33	6.19	*
HDL-C	15.82	-	6.34	9.19	*
LDL-C	14.44	-	4.21	4.26	*
Triglycerides	13.46	-	4.95	2.97	*

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Safety Information

17.3% of patients experienced adverse effects, with constipation (25.48%) and headache (13.55%) being the most common. Only 12/1892 patients were taken off the Protein Diet due to adverse effects.

The Protein Diet using the PronoKal® Method:

- **The patient achieves significant weight loss and BMI reduction at the end of the active and dietary re-education stages, with a high percentage of patients reaching normal weight (33.03%).**
- **>50% of patients who began the diet with alterations in one or more analytical parameters with high cardiovascular risk were able to stabilise these parameters by the end of the dietary re-education stage (12.91% vs. 6.91%).**