



# **PROKAL Study**

# **Study Title**

Open, randomized, controlled clinical trial to evaluate the effectiveness of the PronoKal<sup>®</sup> Method (Protein Diet) vs. a balanced, low-calorie diet for weight loss in obese patients (PROKAL Study).

### **Main Objective**

To evaluate the differences in weight loss between obese patients who follow the PronoKal<sup>®</sup> Method (Protein Diet) vs. obese patients who follow a balanced, low-calorie diet (calorie intake 10% below basal metabolic rate).

#### Study Design and Type

Open, randomized (1:1), controlled, single centre, prospective, nutritional clinical trial with a 2-year follow-up.

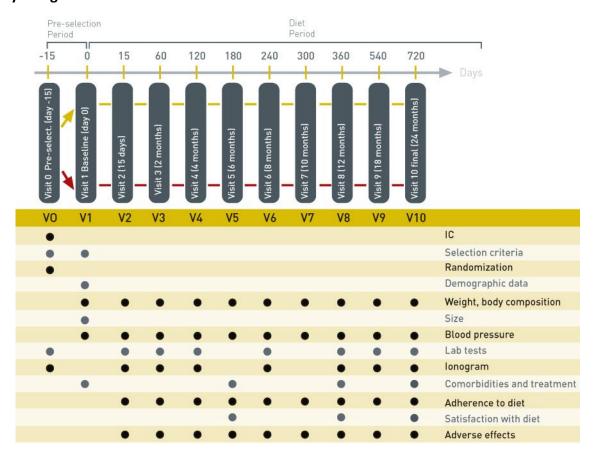
## Centre where the Study was Carried out

Obesity Unit at Gregorio Marañón General University Hospital (Madrid).

## **Study Population**

Obese patients (BMI ≥ 30) between the ages of 18 and 65. All participants signed the informed consent form before inclusion in the study.

## **Study Design**







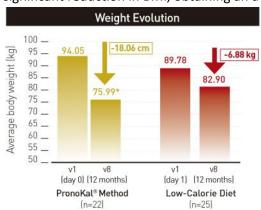
# PRIMARY (PRELIMINARY) RESULTS AFTER 12 MONTHS Sample Characteristics (patients who have completed the 12-month monitoring period)

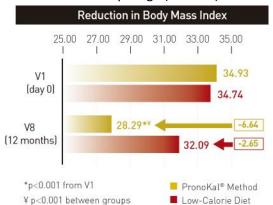
	Baseline Values (visit 1/day 0)	Total n = 53	PronoKal® Method n = 27	Low-Calorie Diet n = 26	p*
Age (years) Average (SD)		45.38 [8.94]	44.44 (8.64)	46.35 [9.32]	N. S.
Sex	Men n [%]	6 (11.32%)	5 (18.52%)	1 (3.85%)	N. S.
	Women n [%]	47 [88.68%]	22 (81.48%)	25 [96.15 %]	N. S.
Weight (kg) Average (SD)		95.17 (18.39)	97.93 [18.91]	92.17 (17.71)	N. S.
BMI (kg/m2) Average (SD)		35.14 (4.94)	35.11 (4.57)	35.18 (5.39)	N. S.
Waist circumference (cm) Average (SD)		109.81 [12.49]	111.31 (13.45)	108.25 (11.46)	N. S.

<sup>\*</sup>Statistical significance. Comparison between groups. N.S.=Not significant.

# Weight Loss and Reduction of Body Mass Index (women only)

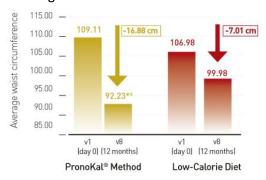
Weight loss over 12 months was 3 times greater with PronoKal®. Only with PronoKal® did patients show a significant reduction in BMI, obtaining an average value below the obesity range (BMI<30).





#### **Evolution of Waist Circumference (women only)**

With PronoKal®, waist circumference reduction is two times greater.



#### Weight-loss Distribution: lean mass/fat mass

With PronoKal®, weight loss is primarily at the expense of fat mass.



93% of patients who followed the PronoKal® Method said they were satisfied (51.9%) or very satisfied (40.7%), versus 88.2% of low-calorie diet patients who were satisfied (61.5%) or very satisfied (26.7%).