



## DIAPROKAL® Study

### Study Title

Open, controlled clinical trial to evaluate the effectiveness of the DiaproKal® Method (Protein Diet) vs. a balanced, low-calorie diet for weight loss in obese diabetic patients (DIAPROKAL® Study).

### Main Objective

To evaluate the safety and tolerability of a Protein Diet as compared to a low-calorie diet (calorie intake 10% below basal metabolic rate, calculated using the FAO/WHO/UN formula) in obese diabetic patients over a period of four months.

### Secondary Objectives

- Evaluate the differences in weight loss between obese diabetic patients who follow the DiaproKal® Method vs. those who follow a balanced, low-calorie diet.
- Evaluate the effectiveness of the DiaproKal® Method vs. the low-calorie diet on metabolic control in obese diabetic patients.

### Study Design and Type

Open, randomized (1:1), controlled, multi-centre, prospective, nutritional clinical trial with a 4-month follow-up.

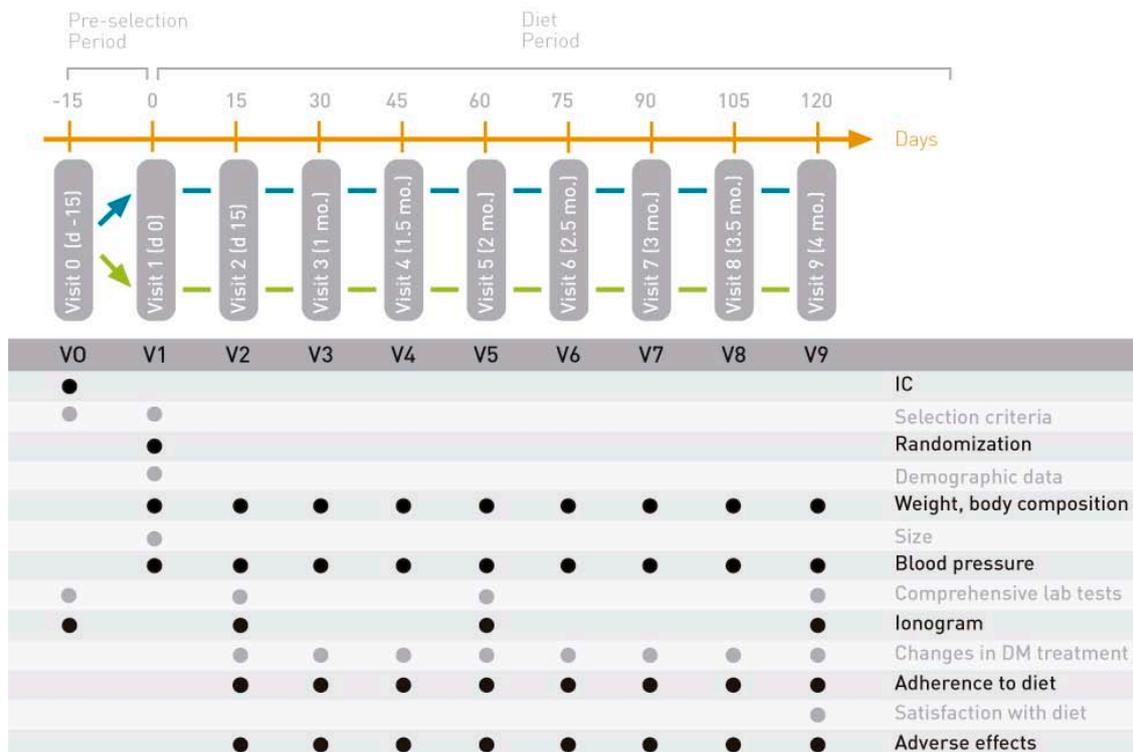
### Centres where the Study was Carried out

The study was carried out in 7 centres in Spain, with the participation of 7 endocrinologists.

### Study Population

Obese type 2, non-insulin-dependent diabetic patients (BMI between 30 and 35), between the ages of 30 and 65. All participants signed the informed consent form before inclusion in the study.

### Study Design





## Sample Characteristics

Baseline Values		Total n = 89	Protein Diet n = 45	Low-Calorie Diet n = 44	P btwn. groups
Age (years) Average (SD)		54.53 (8.37)	54.89 (8.81)	54.17 (7.97)	Not significant
Sex	Men n (%)	31 (34.8%)	15 (33.3%)	16 (36.4%)	Not significant
	Women n (%)	58 (65.2%)	30 (66.7%)	28 (63.6%)	Not significant
Weight (kg) Average (SD)		90.51 (11.37)	91.47 (11.43)	89.54 (11.37)	Not significant
BMI (kg/m <sup>2</sup> ) Average (SD)		33.07 (1.56)	33.25 (1.52)	32.8807 (1.60)	Not significant
Waist circumference (cm) Average (SD)		107.04 (8.54)	108.13 (8.55)	105.94 (8.49)	Not significant

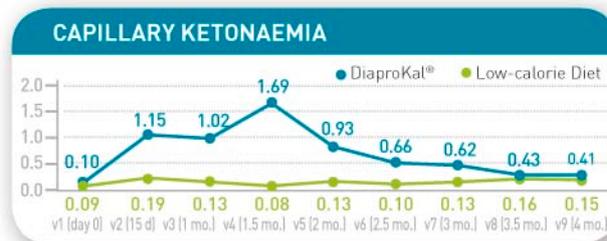
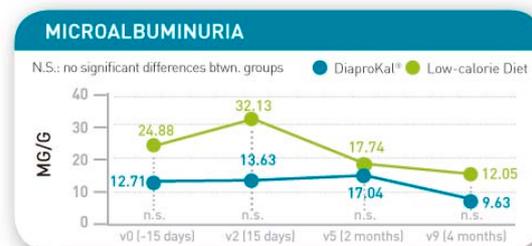
## Safety Information on the DiaproKal® Method in Obese Diabetic Patients

The DiaproKal® Method offers an excellent liver and kidney safety profile for T2DM, with no risk of ketoacidosis.

DPK: DiaproKal® Method; LCD: Low-calorie Diet

\*p<0.05 from V1

Variable		Group	Visit 0 (15d)	Visit 5 (2 mo.)	Visit 9 (4 mo.)
Kidney function	Creatinine [mg/dl]	DPK	0.90	0.84	0.84
		LCD	0.92	0.91	0.90
	Uric acid [mg/dl]	DPK	5.26	5.32	5.12
		LCD	5.20	5.21	5.04
Urea [mg/dl]	DPK	35.93	36.29	38.18	
	LCD	37.48	36.39	35.92	
Liver function	GPT [U/l]	DPK	32.27	26.95	20.45*
		LCD	35.47	25.72	26.72*
	GOT [U/l]	DPK	28.00	25.32	20.80*
		LCD	23.36	22.44	22.75
	GammaGt [U/l]	DPK	39.51	20.88*	25.13*
		LCD	42.65	37.14	33.97
Bilirubin [mg/dl]	DPK	0.55	0.61	0.58	
	LCD	0.56	0.58	0.55	



Ketonaemia levels were slightly higher than normal, but always below levels generally observed in diabetic ketoacidosis.

## Effectiveness Information on the DiaproKal® Method in Obese Diabetic Patients

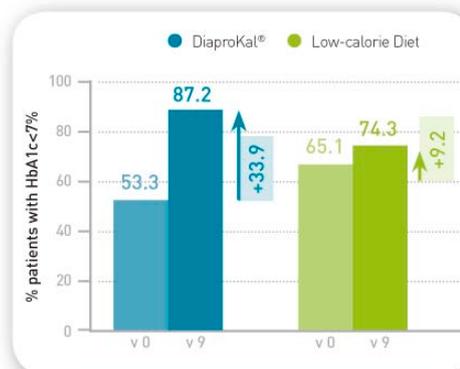
### Weight loss

Patients treated with DiaproKal® lose 3 times more weight and 2 times more waist circumference.



### Control of blood sugar

There is a 33.9% increase in patients with HbA1c<7% in the DiaproKal® group vs a 9.25% increase in the LCD group.



At the end of the study, DiaproKal® was proven to be safe and effective for weight loss in patients with type 2 diabetes, obtaining better blood sugar control as compared to the low-calorie diet.

**Pronokal<sup>®</sup>**  
Rigour and science for weight loss



This document provides scientific information. For further information, please contact us through our website at [www.pronokal.com](http://www.pronokal.com)