ProNoKal®
Rigour and science for weight loss

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.

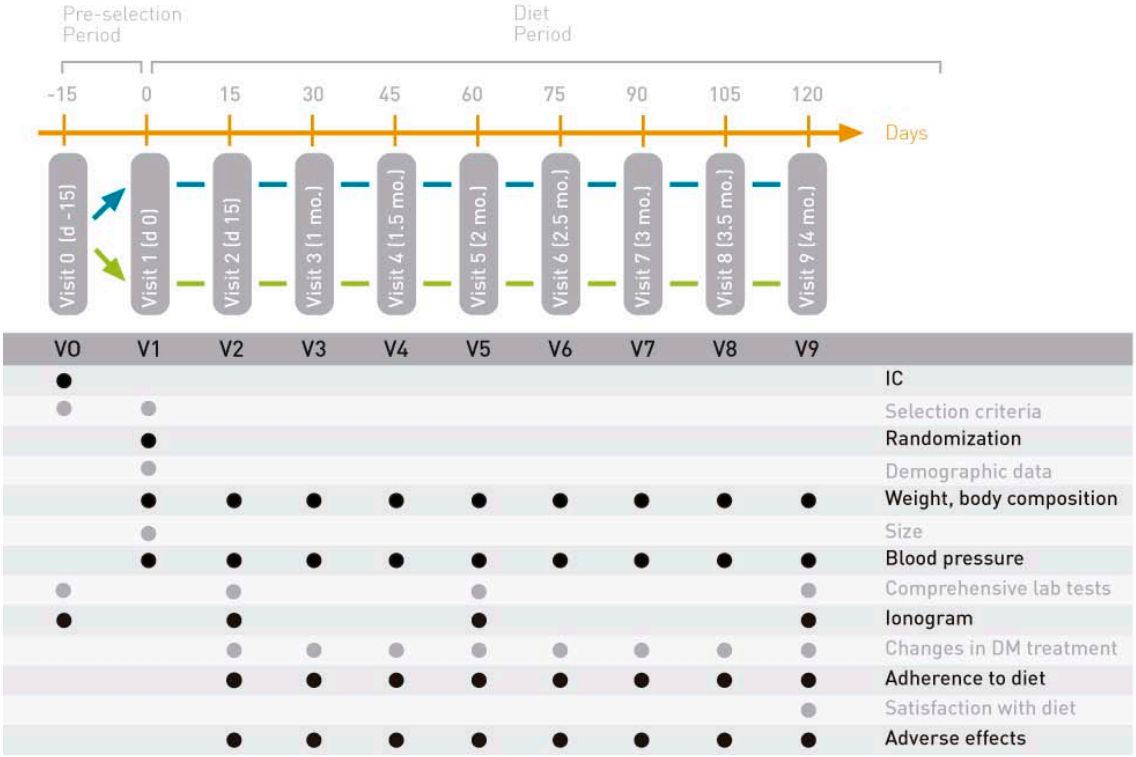
Centres where the Study was Carried out

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 65. All participants signed the informed consent form before inclusion in the study.

Study Design



V0	V1	V2	V3	V4	V5	V6	V7	V8	V9	
●										IC
●	●									Selection criteria
	●									Randomization
	●									Demographic data
	●	●	●	●	●	●	●	●	●	Weight, body composition
	●									Size
	●	●	●	●	●	●	●	●	●	Blood pressure
●		●			●				●	Comprehensive lab tests
●		●			●				●	Ionogram
		●	●	●	●	●	●	●	●	Changes in DM treatment
		●	●	●	●	●	●	●	●	Adherence to diet
									●	Satisfaction with diet
		●	●	●	●	●	●	●	●	Adverse effects

PRIMARY RESULTS AFTER 4 MONTHS

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/m2) 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

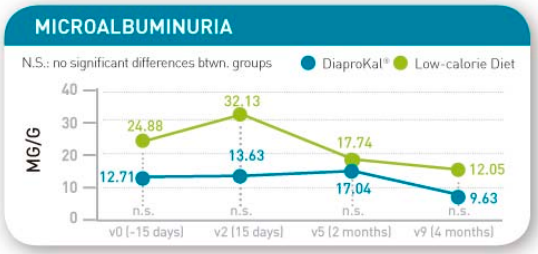
Safety Information on the DiaproKal® Method in Obese Diabetic Patients

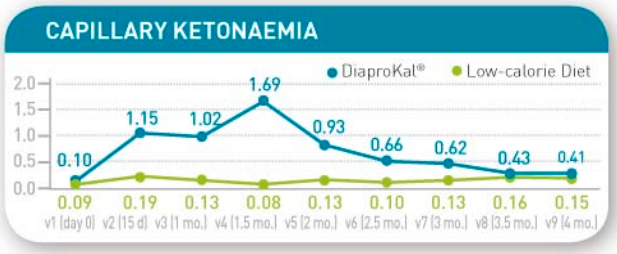
The DiaproKal® Method offers an excellent liver and kidney safety profile for T2DM, with no risk of ketoacidosis.

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	DPK	0.90	0.84	0.84
	(mg/dl)	LCD	0.92	0.91	0.90
	Uric acid	DPK	5.26	5.32	5.12
	(mg/dl)	LCD	5.20	5.21	5.04
	Urea	DPK	35.93	36.29	38.18
	(mg/dl)	LCD	37.48	36.39	35.92
Liver function	GPT	DPK	32.27	26.95	20.45*
	(U/l)	LCD	35.47	25.72	26.72*
	GOT	DPK	28.00	25.32	20.80*
	(U/l)	LCD	23.36	22.44	22.75
	GammaGt	DPK	39.51	20.88*	25.13*
	(U/l)	LCD	42.65	37.14	33.97
	Bilirubin	DPK	0.55	0.61	0.58
	(mg/dl)	LCD	0.56	0.58	0.55



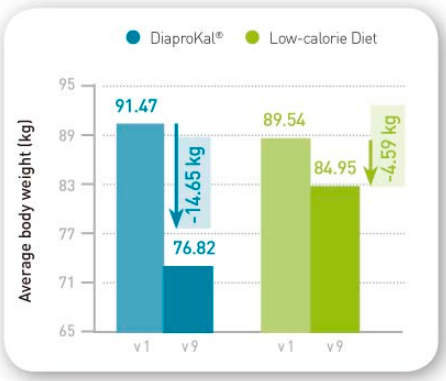


Ketonaemia levels were slightly higher than normal, but always below levels generally observed in diabetic ketoacidosis.

Effectiveness Information on the DiaproKal® Method in Obese Diabetic Patients

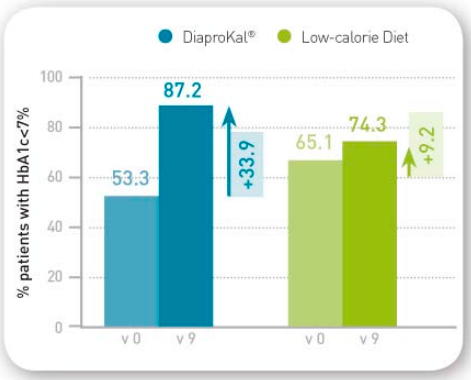
Weight loss

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®

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This document provides scientific information. For further information, please contact us through our website at www.pronokal.com