Preclinical Study and Clinical Correlation of The Effect of PEP2DIA® Dose

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ABSTRACT

BACKGROUND

Prediabetes is a reversible phase of glycemic dysregulation that occurs before type 2 diabetes (T2D). It is therefore important to take in charge prediabetics before they reach diabetic stage. PEP2DIA® is a unique patented dairy bioactive that acts on the main factors leading to T2D.

OBJECTIVE:

A preclinical study with GK rats was performed to evaluate the dose-effect of PEP2DIA®. After validation of the effective dose in rats, a clinical study was conducted to confirm the effective dose in prediabetics.

METHODS:

Preclinical study: GK rats were treated with PEP2DIA® (63; 88.6 and 126 mg/kg) once a day for 6 weeks. At the end of the treatment period, an oral sucrose tolerance test (OSTT) was performed to measure glycaemia, and alpha-glucosidase inhibition was evaluated.

Clinical study: an acute, cross-over, double-blind, placebo-controlled, randomized study was conducted on 36 prediabetics. The clinical study dose was defined using the FDA abacus. PEP2DIA®, 700 mg or 1400 mg, was given 15 minutes before a meal high in carbohydrates (75g) and the postprandial glucose response was assessed.

RESULTS:

In GK rats, PEP2DIA® improved sucrose tolerance with the best effect at 63 mg/kg, with an inhibition of alpha-glucosidase in duodenum. Clinical study confirms that PEP2DIA® 700 mg, equivalent dose to 63 mg/kg in rats, is efficient to affect postprandial glucose response by reduced glucose iAUC compared to placebo in prediabetic responders.

CONCLUSION:

These preclinical data confirmed by clinical study showed that PEP2DIA® reduces blood sugar levels after meal which is beneficial in delaying the onset of T2D.

KEYWORDS:

prediabetes, type 2 diabetes, blood glucose homeostasis, glycemia, milk protein hydrolysate

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