

POSTER PRESENTATION

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# A double blind clinical trial evaluating the relative pharmacokinetics and bioavailability of oral creatine monohydrate when combined with either isomaltulose or dextrose in healthy adult males

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## Background

Isomaltulose (6-0- $\alpha$ -D-glucopyranosyl-D-fructose) is a low-glycemic, low-insulinemic disaccharide that is absorbed more slowly than conventional sugars (monosaccharides). In sports nutrition, creatine monohydrate is often combined with dextrose (a monosaccharide) for the purpose of enhanced absorption and cellular uptake.

## Methods

In a prospective, randomized, double blind, active-comparator-controlled, parallel group pilot study, 30 male subjects, age  $27.0 \pm 4.6$  years, with BMI of  $24.75 \pm 1.99$  kg/m<sup>2</sup> and a body surface area (BSA) of  $1.953 \pm 0.075$  m<sup>2</sup>, were randomly assigned to ingest 3 grams of creatine monohydrate (CM) in combination with isomaltulose (ISO) or dextrose (DEX) in 1 of 3 concentrations (5 gm liquid, 17 gm capsules or 50 gm liquid). Rate of absorption ( $t_{Max}$ ) and overall absorption (from BSA adjusted  $AUC_{0-8h}$  and  $C_{Max}$ ) of CM was determined via changes in serum creatine over an 8-hour test period. Blood was collected at baseline and 0.5, 1, 2.5, 4 and 8 hours post ingestion with efficacy endpoints including  $C_{Max}$ ,  $t_{Max}$ ,  $AUC_{0-8h}$  and  $\lambda_{Elim}$  derived from normalized concentration vs. time curves for serum creatine (AUC by trapezoidal integration). Serum creatine levels were normalized by BSA using the Mosteller formula. For PK parameters, paired Student t test (or Wilcoxon if non-

normally distributed) was used and for categorical variables, Fisher Exact test (or Chi-Square if necessary) was used. Statistics were calculated by R v2.14.0 ([www.r-project.org](http://www.r-project.org)).

## Results

For the 17 gm concentrations, ISO had a significantly higher  $C_{Max}$  than DEX ( $18.1 \pm 1.5$  vs  $12 \pm 1.6$  mg/dl\*m<sup>2</sup>;  $p < 0.001$ ) and for the 50 gm concentrations, the  $C_{Max}$  trended higher for ISO than DEX ( $19.1 \pm 6.4$  vs  $13.1 \pm 3.3$  mg/dl\*m<sup>2</sup>;  $p = 0.099$ ). The AUC for the 50 gm concentration was significantly higher for ISO than DEX ( $54.6 \pm 9.2$  vs  $40.3 \pm 10$ ;  $p = 0.046$ ). The 17 gm ( $1.9 \pm 0.8$  hrs) and 50 gm ( $1.3 \pm 0.7$  hrs) concentrations were associated with larger  $t_{Max}$ , which trended toward significance over the 5 gm concentration ( $1 \pm 0$  hrs) for ISO ( $p = 0.078$ ) and was not significant for DEX. For all 3 concentrations, the  $C_{Max}$  and AUC were significantly higher for ISO than DEX ( $17.8 \pm 4.7$  vs  $13.5 \pm 2.8$  mg/dl\*m<sup>2</sup> and  $50.8 \pm 17.1$  vs  $38.8 \pm 10.3$ ;  $p = 0.005$  and  $p = 0.027$  respectively).

## Conclusions

CM appears to be absorbed more efficiently when combined with ISO over DEX supported by a significantly higher  $C_{max}$  for the 17 g concentration and a significantly higher AUC for the 50 g concentration. The 17 and 50 gm formulations appear to be superior to the 5 gm concentration. ISO appears to be a beneficial carbohydrate for facilitating the delivery of creatine to the body.

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