

## A24

### A comparative pharmacokinetic evaluation of caffeine in two different delivery vehicles in healthy adults

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#### Background

The purpose of this prospective pharmacokinetic (PK) study was to evaluate two different delivery systems for caffeine in healthy adults. Caffeine is found in foods, beverages and in dietary supplements. Athletes often utilize caffeine as an ergogenic aid for sport and mental performance. The timing of caffeine ingestion for ergogenic use has typically been centered on timing for events that commence within an hour of dosing, however for events of longer duration, caffeine dosing may not have the desired impact. Sustained or delayed release caffeine may have ergogenic use for athletes who engage in prolonged training or who want to customize their caffeine experience.

#### Materials and methods

In a prospective randomized two-way counterbalanced cross over pharmacokinetic trial, 12 healthy adults (35.8±11.62 y.o., BMI of 26.67 ±4.63 kg/m<sup>2</sup>, 7 males, 5 females) under standardized conditions were given either Immediate Release Caffeine 250mg (IR) or Extended Release Caffeine 250 mg (ER; zümXR<sup>®</sup>, Nano Pharmaceuticals, Denver, CO.) with the opposite administered after a three-day washout. Subjects were dosed and plasma caffeine was measured over a 12 hr post-dose period. Plasma caffeine was measured by LC MS/MS (Keystone Bioanalytical). The PK profile for T<sub>max</sub>, C<sub>max</sub> and terminal ½ life was determined by linear mixed effects model. Standard statistical techniques were also used.

#### Results

Dissolution tests of the raw material revealed that the IR caffeine delivers 100% of the caffeine within 1 hour. The ER caffeine (ZümXR<sup>®</sup>) was found to deliver 26% caffeine by 1 hour and 79% by 6 hours. The Per Protocol analysis (n=12) revealed that the IR caffeine had a C<sub>max</sub> of 7.42 ± 1.78 ug/ml, T<sub>max</sub> of 1.0 hr and a half-life (t ½ h) of 6.38 ± 2.71 hr. In contrast, the ER caffeine (zümXR<sup>®</sup>) had a C<sub>max</sub> of 3.66 ± 1.13 ug/ml, a T<sub>max</sub> of 4.0 hr and a half-life (T ½ h) of 10.5± 5.12 hr.

#### Conclusions

This study demonstrated that the ER caffeine has a different and extended PK profile relative to the IR caffeine. The ER caffeine exhibited a 300% longer T<sub>max</sub> and 64.6% longer half-life than the IR caffeine. This human data supports the dissolution data, adding strength to the overall findings. ER caffeine such as zümXR<sup>®</sup> technology may have application for athletes who desire extended circulating levels of caffeine.

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