Comparative pharmacokinetic evaluation of a new formulation of vitamin C gel caps

Bela E Toth[1], Istvan Takacs[2], Boglarka Szabo[2], Bence Bakos[2] and **Janos Torok[3]**
[1]University of Debrecen, Hungary
[2]Semmelweis University School of Medicine, Hungary
[3]Fumoprep Laboratories, Hungary

Objective: The objective of the pharmacokinetic study was to demonstrate efficacy and the bioavailability of new formulation of Vitamin C in gel caps, comparing that to the controlled release formulation in vitamin C depleted healthy volunteers.

Methodology: Adult subjects with vitamin C levels <75 micromol/L at screening were enrolled according to the inclusion and exclusion criteria. Volunteers randomly assigned to one of the following groups: Vitamin C i.v. injection 500 mg, p.o. controlled release 500 mg capsules, p.o. NovoC Plus 2x300 mg softgel capsules dietary food supplement. The comparative efficacy and bioavailability was assessed by the serum levels and the urinary ascorbate levels.

Results: Intravenous administration resulted in a shirt peak with a quick turnover within 3 hours. Oral administration of controlled release capsules or the new formulation of NovoC Plus softgel capsules resulted in statistically similar extended (elongated) kinetics within 12 hour-investigational period similar to that of the (timed) controlled release product claimed. Considering the availability, the normalized AUC were not different, however higher dose response were detected in serum (i.e. capacity of the given dose to increase of ASC levels in blood) compared to levels that was achieved by the controlled release capsules.

Conclusion & Significance: The treatment with the new formulation NovoC Plus resulted in similar AUC response, high bioavailability and extended duration of vitamin C supplementation in serum compared to the (timed) controlled release capsules. The effect presumably due to the modified/alternative absorption kinetics resulted in the liposomal/lipoid components of the formulation. The oral administration of the similar or lower doses of this new formulation may give better or more time-efficient availability of ASC in blood to support the tissues in conditions of increased amount required or such as stress, muscular depletion in (extreme) sports or other medical conditions.

Speaker Biography

Istvan Takacs has his academic background based on Neuroendocrine and Cell Biology Research (Semmelweis University, Neuroendocrine research group at Academy of Sciences Hungary; Rudolph Magnus Institute of Pharmacology, Utrecht: The Netherlands; Dept. of Molecular and Cell Biology: Penn State University, USA). He served as a university Lecturer (Medical School) and invited Lecturer for graduate and postgraduate education and recently appointed as Associate Professor, Head of Department pf Pharmaceutical Surveillance and Economy at Debrecen University, teaching pharmacovigilance, pharmaceutical business-management, and drug development. His clinical research experience is based on clinical operation management and clinical quality site management including senior level consultancy for pharmaceutical industry (research /project management, drug development, medical affairs) and clinical operational head. His research project covered the range of development phases (I/II to III-IV) including specific areas such as bioequivalence and post-marketing safety trials as well.

e: tothe.bela@pharm.unideb.hu

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