Clinical Study on Determining the Bioavailability of Coenzyme Q10 and Vitamin E

Within the framework of the study, the bioavailability of a micellised coenzyme Q\textsubscript{10} and vitamin E – formulation (NanoSolve) - was tested against the raw product (powder form in a capsule) on a defined collective.

The goal of the study is the characterisation of bioavailability on the basis of the pharmacokinetic parameters $C_{\text{max}}$, $T_{\text{max}}$ and AUC in plasma. After the test preparations were taken for a period of 14 hours at defined points of time, blood samples were taken to determine the vitamin E and coenzyme Q\textsubscript{10}.

The selected cross-over design enables a direct comparison between the formulations; that means: each subject took both the raw product (vitamin E; coenzyme Q\textsubscript{10}) and the micellised form (NanoSolve technology).

General graphic view

The study design was approved by the Ethics Committee of the Institutional Review Board of Baden-Württemberg (Germany).

On the basis of inclusion and exclusion criteria, 24 voluntary, healthy subjects, 12 women and 12 men, were enrolled in the study. The health was checked by taking an anamnesis, carrying out a physical examination and the determination of routine blood parameters. The following table briefly summarises the included collective.
Concentration-time-curve after single dose of vitamin E

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Reference area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [years]</td>
<td>26.7 ± 6.8</td>
<td>18-50</td>
</tr>
<tr>
<td>Body mass index [kg/m²]</td>
<td>22.2 ± 2.4</td>
<td>19-30</td>
</tr>
<tr>
<td>Cholesterol [mg/dL]</td>
<td>189 ± 29</td>
<td>110-250</td>
</tr>
<tr>
<td>Coenzyme Q₁₀ [µmol/L]</td>
<td>0.62 ± 0.14</td>
<td>0.52-1.27</td>
</tr>
<tr>
<td>Vitamin E [µmol/L]</td>
<td>25.4 ± 4.1</td>
<td>15-45</td>
</tr>
</tbody>
</table>

In total, the group is a representative group to enable examination of the question.

The test preparations (100 mg coenzyme Q₁₀ and 120 mg vitamin E) were taken as a single dose after overnight fast. The blood samples took place through an in-dwelling catheter. The subjects were under medical supervision for the duration of the clinical examination. Standardised meals minimise influencing external factors.

The pharmacokinetic parameters $C_{\text{max}}$, $T_{\text{max}}$, and $AUC$ were determined after a single dose from the analysed concentrations of vitamin E and coenzyme Q₁₀ in the blood (HPLC technology).

The $C_{\text{max}}$ value represents the maximum achieved increase in concentration of the parameter observed in the plasma.

$T_{\text{max}}$ describes the point of time at which the maximum concentration of the parameter observed in the plasma is reached.

$AUC_{0-14h}$ is a measure for the general bioavailability as the area under the concentration-time-curve.

The bioavailability is a value for how quickly and to which extent a substance is resorbed and is available to the body.

To take the concentration fluctuations in the blood caused through liquid, the values were also corrected to the plasma share.
Results of the study:

**Coenzyme Q\textsubscript{10}**

The distribution of the pharmacokinetic parameters is shown. It can be clearly recognised that, through NanoSolve technology, significantly higher concentrations in the plasma are achieved and coenzyme Q\textsubscript{10} floods the blood more quickly and achieves maximum concentration earlier.

The area under the concentration-time-curve is increased with the NanoSolve technology; that means that the body has 5 times more CoQ\textsubscript{10} at its disposal on the average (median).

**Vitamin E**

Analogously to the results of CoQ\textsubscript{10}, it can be recognised that through the NanoSolve technology, a significantly higher concentration is achieved in the plasma, that
vitamin E floods the blood more quickly and that the maximum concentration is achieved earlier.

The area under the concentration-time-curve is significantly increased with NanoSolve technology; that means that the body has 10 times more vitamin E at its disposal on the average (median).

**Summary:**

1. The study design guarantees standardised conditions with respect to exogenous factors of influence.
2. The volunteer collective represents in all tested characteristics to a representative group of young healthy people.
3. The micellised formulation (NanoSolve) shows the following characteristics on the basis of the pharmacokinetic parameters $T_{\text{max}}$, $C_{\text{max}}$ and $AUC_{0-14h}$ towards the comparative formulation (raw product in capsule):
   a. The NanoSolve technology conveys a significantly higher $\text{CoQ}_{10}$ and vitamin E concentration in the blood than the comparative formulation.
   b. With the aid of the NanoSolve technology, $\text{CoQ}_{10}$ and vitamin E flood the blood significantly more quickly than with the comparative formulation.
   c. The area under the concentration-time-curve is significantly increased with the NanoSolve technology; that means that the body has more active ingredients at its disposal. The bioavailability of the ingredients is in average (median) 5 to 10 times better.

Although a clearly inter-individual variability of the bioavailability is observed from person to person, a clear superiority of the NanoSolve formulation over the non-micellised raw product can be clearly proven in respect of the bioavailability parameter.