EFFECT OF NUTRITIONAL STATUS AND GESTATIONAL AGE ON THE PHARMACOKINETICS OF RANITIDINE IN NEWBORN CHILDREN

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Background and aims The purpose of this study was to develop a population pharmacokinetics model (Pop PK) for ranitidine in newborns, and to determine the effect of the nutritional state (NS) and gestational age (GA). The protocol was approved by the bioethics committee.

Methods Fifty newborns (20 females and 30 males) were included. Their (GA) was as follows: 6 pre-term, small (SGA); 20 pre-term, appropriate (AGA); 4 pre-term, large (LGA); 7 SGA of full term; and 13 AGA of full term. Children received 3 mg/kg/day IV bolus of ranitidine; two blood samples were collected at each of the following times obtained randomly to: 0, 0.5, 0.75, 1, 2, 4, and 8 h from every newborn. The ranitidine levels were determined using HPLC technique. For the population pharmacokinetics (Pop PK) of ranitidine was used with MONOLIX MLXTRANS 4.2.2® program; data were fitted to bicompartimental model with first-order kinetics.

Results The population values without effect of covariates were obtained clearance (CL) = 0.267 mL/min (CV = 0.683); volume of distribution (VD1) = 0.860 L (CV = 0.0642); VD2 = 0.260 L (CV = 0.47); intercompartmental clearance (Q) = 1.35 (0.279 mL/min). The covariables that influences clearance of ranitidine were: (GA) and had one of the poorest survival rates.

Conclusions Pharmacokinetics of ranitidine depend on (GA) and (NS) of the newborns. This should be considered to determine an adequate dosage treatment, based on respective Pop PK characteristics.

Poster symmetry

Abstract PS-232 Table 1

<table>
<thead>
<tr>
<th>Control</th>
<th>Group</th>
<th>IVH</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grades</td>
<td>Days</td>
<td>KIM-1 (ng/mL)</td>
<td>uNGAL (ng/mL)</td>
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<tr>
<td>1–3</td>
<td>3–7</td>
<td>10.0 ± 2.2</td>
<td>8.9 ± 1.5</td>
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*0.05 < p < 0.05 – relative to the IVH I-II group

**p < 0.05 – relative to the control group

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