

(35%); cardiac (19%); non-cardiac anomaly (15%) and syndromal (12%). Of the 52 infants born alive, 20 (39%) survived to hospital discharge. Survival with idiopathic hydrops was 28%.

**Conclusions** Overall survival in infants born alive with hydrops was 39%. Idiopathic hydrops was the most common diagnosis and had one of the poorest survival rates.

# PS-231 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 nutritional state (NS) and gestational age (GA). The protocol was approved by the bioethics committee.

**Methods** Fifty newborn (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<sup>®</sup> 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 = 0.685); volume of distribution (Vd<sub>1</sub>) = 0.860 L (CV = 0.0642); Vd<sub>2</sub> = 0.260 L (CV = 0.47; intercompartmental clearance (Q) = 1.35 (0.279 mL/min. The covariables that influences clearance of ranitidine are gestational age (term infants from 37 to 42 weeks) with decreased CL = 0.241 mL/min, p = 0.008. The BW increase the Vd<sub>1</sub> = 1.03 L and reduces the value of Q = 0.556 mL/min (CV = 0.049).

**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.

# PS-232 DETERMINATION OF RENAL HYPOXIC INJURY IN LBW INFANTS WITH IVH USING NEW BIOMARKERS - KIDNEY INJURY MOLECULE 1 (KIM-1) AND URINARY NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (UNGAL)

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**Background** The brain tissue is very sensitive to hypoxia-ischemia and all the changes occurring within it are well studied and

## Abstract PS-232 Table 1

	Grades	Days	KIM-1 (ng/ml)	uNGAL (ng/ml)	Renal Artery RI
<b>Control Group</b>	I-II	1-3	0.3 ± 0.03	21.6 ± 5.9	0.5 ± 0.03
		7-10	0.24 ± 0.02	18.8 ± 3.1	0.7 ± 0.06
<b>IVH Groups</b>	I-II (n = 43)	1-3	0.422 ± 0.04	40.1 ± 17.3	0.98 ± 0.01
		7-10	5.313 ± 0.089*	39.1 ± 16.3*	1.1 ± 0.03
<b>IVH Groups</b>	III-IV (n = 25)	1-3	0.8 ± 0.01*^	45.9 ± 0.5	1.7 ± 0.05*
		7-10	6.95 ± 0.2^	58.0 ± 0.2*^	1.3 ± 0.01

^p < 0.05 - relative to the IVH I-II group

\*p < 0.05 - relative to the control group

easily diagnosed through laboratory and instrumental methods of examination. In contrast, there are few studies examining the influence of hypoxia-ischemia on kidneys in LBW newborns.

**Aim** To determine the degree of hypoxic-ischaemic renal injury in LBW infants with various grades of IVH using new biomarkers of renal injury such as KIM-1 and uNGAL.

**Methods** We studied 68/94 LBW infants (GA 28-36 weeks) with IVH (IVH grades I-II (N = 43) and III-IV (N = 25)) and conducted neurosonography and Doppler ultrasound tests of renal arteries. Urine samples were collected on days 1-3 and 7-10 after birth to determine KIM-1 and uNGAL levels.

**Results** The comparison of the IVH groups I-II and III-IV (Table 1) and the control group (N = 26) shows that the levels of biomarkers KIM-1 and uNGAL significantly increased in grades III-IV IVH infants (p < 0,05).

**Conclusion** This study finds that severity of renal damage depends on the grade of IVH and shows that KIM-1 and uNGAL are the most sensitive and early markers of hypoxic damage of tubular parts of a kidney.

## PS-233 ACTIGRAPHY IS NOT A RELIABLE METHOD FOR SLEEP STUDIES IN NEONATES

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**Background and aims** Sleep is an essential physiological function in newborn development. Polysomnography is the gold standard for sleep analysis. Extended recordings are difficult with this method. To evaluate actigraphy's reliability to determine sleep-wake patterns in newborns in comparison with polysomnography.

**Methods** Prospective, monocentric study. 48 infants sleep patterns were recorded and assigned into two groups: group 1: 24 preterm neonates at 34-36 weeks gestational age (GA); group 2: 24 term neonates. Polysomnography (PSG) and 2 actigraphs (ACT) Actiwatch Mini<sup>®</sup> [on arm (arm-ACT), on leg (leg-ACT)] were used during a 3-hour period. Primary endpoint: agreement rate (AR) PSG and leg-ACT with Medium activity threshold setting. Secondary endpoint: AR arm-ACT and leg-ACT. AR's threshold was set at 85% for validation purposes. Effect of ACT activity threshold setting on a sample of 11 newborns was evaluated.

**Results** GA, birth weight and age at the recording: 34.5 weeks ± 0.5 and 39.2 ± 1.1, 2368 g ± 336 and 3393 ± 439, 6.4 days ± 2.8 and 2.54 ± 0.72 respectively for group 1 and 2. Group 1: AR PSG and leg-ACT was 67% ± 17 [95% CI, 60-74] and group 2: 58% ± 17 [95% CI, 51-65]. Group 1: AR arm-