and in weight and length at 12 and 18 months CA in infants born \geq 1250g; reduction in hayfever at either 12 or 18 months CA in male infants, RR 0.15 (0.03, 0.64), P=0.01; reduction in supplemental oxygen use at 36 weeks PMA in male infants, RR 0.67 (0.47, 0.96), p=0.03 and in all infants < 1250g; RR 0.75 (0.57, 0.98), p=0.04.

Conclusions: DHA supplementation in infants < 33 weeks gestation does not negatively affect growth, reduces bronchopulmonary dysplasia in male infants and in all infants < 1250g and reduces hayfever in male infants.

146

A RANDOMIZED, DOUBLEBLIND CROSSOVER STUDY COMPARING RHBSSL (RECOMBINANT HUMAN BILESALTSTIMULATED LIPASE) AND PLACEBO ADDED TO INFANT FORMULA IN PRETERM INFANTS

L. Maggio¹, M.P. Bellagamba², S. Costa¹,
C. Romagnoli¹, M. Rodriguez³, K. Timdahl⁴,
M. Vågerö⁴, V.P. Carnielli²

¹Policlinico 'Agostino Gemelli'- Università Cattolica del Sacro Cuore, Roma, ²Polytechnic University of Marche and Azienda Ospedaliero Universitaria Ospedali Riuniti 'Umberto I-G.M. Lancisi-G.Salesi', Ancona, Italy, ³Dirección General Científica, Laboratorios Ordesa, Barcelona, Spain, ⁴Clinical Development, Swedish Orphan Biovitrum, Stockholm, Sweden

Background: The rationale for enzyme replacement therapy with rhBSSL in preterm infants is to restore the natural lipase activity that is absent when mother's milk is replaced with infant formula or human pasteurized milk.

Objectives: To compare the CFA of total fat and of selected fatty acids, as well as growth and safety in preterm infants treated with 0.15 g/L rhBSSL or placebo. 33 infants with a mean (\pm SD) weight of 1494 \pm 195 g and GA 32.6 \pm 0.46 weeks were randomised at 3.4 \pm 1.19 weeks of life to receive one-week treatment with rhBSSL and placebo in a crossover design. 32 infants completed the study and 26 were evaluable for CFA.

Results: During rhBSSL treatment a small but not statistically significant increase in total CFA (2.1%) was observed as compared to placebo. A statisticially significant improvement in weight of 3.7 g/kg/day (95% CI:1.6 to 5.9) with rhBSSL (mean 18.1 SD 3.96) compared to placebo (mean 14.3 SD 6.49) (p=0.001) was observed. There was a trend towards improved intestinal absorption of docosahexanoic acid and arachidonic acid (7.1% and 6.8% respectively) with rhBSSL.

One serious adverse event occurred during the study but was not related to study drug. No difference in tolerability between rhBSSL and placebo was seen.

Conclusion: In this first clinical study of rhBSSL in preterm infants a statistically significant increase in weight gain was observed. After one week of treatment, there was no significant difference in CFA. The safety and tolerability profile of rhBSSL added to formula was similar compared to placebo.

147

BIOCHEMICAL AND NON-INVASIVE BRAIN MONITORING IN NEWBORNS WHOSE MOTHERS USED ANTIDEPRESSANTS DRUGS DURING PREGNANCY

V. Bellissima¹, S. Miriam¹, M. Colivicchi¹, F. Guerriero¹, M. Strozzi¹, T. Ververs², F. van Bel³, D. Gazzolo¹

 ¹Ospedale Infantile Cesare Arrigo, Alessandria, Italy, ²University Medical Center Utrecht,
³University Medical Center Utrecht, Wilhelmina Children's Hospital, Utrecht, The Netherlands

Background and aims: The use of antidepressant drugs such as selective serotonin reuptake inhibitors (SSRI) during pregnancy is increasing to up 2% of pregnant women. It is been shown both in human and in animal models that SSRI exposure during pregnancy can have side-effects on whole organs including Central Nervous System (CNS). In this regard, tremors, irritability, disturbed sleep regulation, feeding problems, neonatal convulsions and respiratory distress have been reported. Therefore, the present study is aimed at investigating whether the concentration in maternal and neonatal biological fluids of a well-established biochemical marker of brain development and damage, namely S100B protein, can vary according to SSRI exposure.

Methods: An observational study was conducted in 25 pregnant women exposed to SSRI and in 25 healthy pregnancies as controls. S100B protein was measured at different pregnancy time-points (at 26, 30, 34 wks and at delivery) in maternal blood, at delivery in arterial and venous cord blood and at 24-h after birth in newborns.

Oral Abstracts

Results: S100B maternal and neonatal blood concentrations were significantly higher at all monitoring time-points in the SSRI (P< 0.001, for all), whilst proteins' concentrations in healthy mothers and newborns were within normality ranges.

Conclusions: The elevated S100B protein concentrations in maternal and newborn bloodstreams suggest that SSRI exposure, in agreement to adults' findings, can exert CNS sideeffects both in intrauterine and in post-natal periods. Further investigations aimed at investigating short/ long term neurological sequelae in these patients are needed.

148

BRANCHED CHAIN AMINO ACID REQUIREMENTS FOR TERM NEONATES

F. Maingay-de Groof¹, L. Huang¹, G.J. Voortman¹, C. Chao², Y. Huang², J.B. van Goudoever¹

¹Neonatology, Pediatrics, Erasmus MC Sophia, Rotterdam, The Netherlands, ²Neonatology, Pediatrics, Fudan Children's Hospital, Shanghai, China

Background: Dietary intake should meet the requirement to obtain an optimal growth and neurodevelopment in the neonate. The essential branched chain amino acids (BCAAs), leucine, isoleucine and valine, are mainly used for incorporation into body protein. Current recommended BCAA requirements for infants 0-6 months (respectively 156, 88 and 87 mg·kg⁻¹·d⁻¹, ratio 1.8:1:1) are based on the amino acid content of human milk. However, human milk fluctuates in composition during lactation and even during a feeding, while milk consumption rate varies widely as well. Questions remain on the validity to use mean amino acid composition of human milk to determine requirements.

Objectives: To quantify the requirement of leucine, isoleucine and valine in term neonates using the Indicator Amino Acid Oxidation method.

Design: Enterally fed term infants received randomly graded intakes of leucine (15-500 mg·kg⁻¹·d⁻¹), isoleucine (5-216 mg·kg⁻¹·d⁻¹) and valine (5-236 mg·kg⁻¹·d⁻¹). Breath samples containing ¹³CO2 were collected during L-[1-¹³C]phenylalanine (indicator amino acid) administration, measured by isotope ratio mass spectrometry and analysed using a biphasic regression crossover analysis.

Results: 83 term Asian neonates (birth weight: 3.29 \pm 0.4 kg, gestational age: 39.4 \pm 1.3 wks, postnatal age: 12.6 \pm 5.1 d) were included. The mean requirement (at breakpoint) for leucine, isoleucine and valine was respectively 140, 105 and 110 mg·kg⁻¹·d⁻¹ and the upper 95% confidence interval was 240, 152 and 165 mg·kg⁻¹·d⁻¹.

Conclusion: The requirements of the individual BCAAs are almost twice the current recommendations. A Leu:IIe:Val ratio of 1.3:1:1 is more appropriate in term formula.

149

GESTATIONAL AGE PATTERNS OF FETAL AND NEONATAL MORTALITY RATES: THE EURO-PERISTAT PROJECT

A. Mohangoo¹, S. Buitendijk¹, J. Zeitlin², and the EURO-PERISTAT Network

¹Prevention and Care, TNO Quality of Life, Leiden, The Netherlands, ²Epidemiological Research Unit on Perinatal and Women's Health, INSERM UMR S16, Paris, France

Background: The recently published European Perinatal Health Report showed wide variability in perinatal mortality rates between European countries. We investigated the gestational age patterns of mortality in order to better understand differences between low versus high mortality countries.

Setting: The Euro-Peristat project developed a list of valid and reliable indicators for monitoring and evaluating perinatal health, including fetal and neonatal mortality. Data from 2004 on 29 countries/ regions were analyzed.

Results: The fetal mortality rate ranged from 2.6 per 1000 births in Slovakia to 9.1 in France (weighted average of 5.4 per 1000 births) and the neonatal mortality rate ranged from 1.6 per 1000 live births in Cyprus to 5.7 in Latvia (weighted average of 3.0 per 1000 live births). In some countries, fetal mortality rates declined dramatically after excluding extremely preterm births (< 28 weeks), while elsewhere rates stayed stable. The exclusion of the extremely preterm births hardly influenced the variability in neonatal mortality rates, although a large decline was observed for the Netherlands, where active intervention is very conservative before 26 weeks of pregnancy. We did not find that countries with low mortality rates had higher proportions of extremely preterm births (which could be considered less