neurodevelopmental follow-up to determine their long term outcomes.

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INCIDENCE, RISK FACTORS AND SEVERITY OF PULMONARY MORBIDITY IN INFANTS WITH CONGENITAL DIAPHRAGMATIC HERNIA BORN IN HIGH-VOLUME CENTRES IN EUROPE

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Background and aims: Newborns with congenital diaphragmatic hernia (CDH) may develop chronic lung disease (CLD). Our aim was to determine the incidence, severity and risk factors of CLD in infants with CDH.

Methods: Data were collected about 426 CDH patients born between 2005 and 2008 at 8 high-volume centres (> 10 admissions of infants with CDH per year) in Europe. The primary endpoint was CLD, defined as oxygen dependency at day 28. The severity of CLD (mild: ${\rm FiO_2}~0.21$; moderate: ${\rm FiO_2}~0.22$ -0.29; severe: ${\rm FiO_2}~0.30$ or CPAP/mechanical ventilation) was determined at day 56 or at discharge, whichever came first.

Results: At day 28, the mortality rate was 28% and the CLD incidence was 31%. Of all patients with CLD, 31% had severe CLD, 15% moderate CLD and 54% had mild CLD. Compared to patients without CLD, patients with CLD had a lower lung-to-head ratio (p< 0.001), more often had an intrathoracic liver position (p< 0.001), required treatment for pulmonary hypertension (p< 0.001), had a patch repair (p< 0.001), developed a pneumothorax (p< 0.001) and required ECMO (p< 0.001). Independent risk factors for CLD were an intrathoracic liver position (OR 5.9, 95% CI 3.9-10.4) and a lower gestational age at birth (OR 0.86, 95% CI 0.73-0.97). Patients with severe CLD more often had a

pneumothorax (p< 0.001), patch repair (p=0.035) and ECMO treatment (p< 0.001) than patients with mild to moderate CLD.

Conclusion: Pulmonary morbidity, which is a major problem in infants with CDH, can be identified antenatally.

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CLINICAL AND GROWTH OUTCOMES FROM THE DINO (<u>D</u>HA FOR THE <u>IMPROVEMENT</u>
OF <u>NEURODEVELOPMENTAL OUTCOME</u> IN PRETERM INFANTS) TRIAL

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Background and aims: Higher-dose docosahexaenoic acid, DHA, (~1% total fats) compared with standard-dose (~0.3%) in infants born < 33 weeks gestation improved the mental development of girls (JAMA, 2009). We report the effect on growth, allergic and respiratory symptoms.

Methods: Multicentre randomised controlled trial, stratified for sex, birth-weight (< 1250g, ≥1250g) and centre. Lactating women took tuna oil capsules (higher-dose DHA) or soy oil (standard); preterm infant formula with matching DHA composition was given if needed. Data collection included weight, length and head circumference weekly in-hospital and at term, 4, 12 and 18 months corrected age (CA); oxygen supplementation at 36 weeks post menstrual age (PMA) and parental reporting of medical diagnosis or drug treatment for atopic conditions.

Results: 657 infants were enrolled, 93.5% completed 18-month follow-up. Significant benefits were seen in infants receiving higher-DHA, including greater length (0.7 cm) at 18 months CA (95% CI 0.1, 1.4 cm, P=0.02); increases in length at 4 months CA

and in weight and length at 12 and 18 months CA in infants born ≥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.

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

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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 (±SD) weight of 1494±195 g and GA 32.6±0.46 weeks were randomised at 3.4±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.

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

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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 \$100B 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.