ranged from 1 week to 6 years with Hi-F duration of 3 days to 5 years. 24-hour urine free cortisol (UFC) levels were 17 - 301 times the upper reference range (RR) during Hi-F periods. During Eu-F, lowest UFCs were within RR in 9 patients and subnormal in 3. Hypokalemia occurred in 11 patients with Hi-F; increasing values paralleled movement to Eu-F.

Conclusion: Patients with possible ectopic ACTH-secretion and CCS may pose a diagnostic challenge: clinical and biochemical evidence of hypercortisolism may not be present, depending on the timing and/or duration of hypercortisolism. Furthermore, test results may inappropriately suggest Cushing’s disease if performed after less than 8 weeks of hypercortisolism, or with recent eucortisolism. Thus, weekly UFC measurement may facilitate diagnosis of cyclical Cushing’s syndrome and determine appropriate timing of dynamic testing such as inferior petrosal sinus sampling. Potassium may be a useful marker to determine when medical treatment can be tapered or stopped.

1. Meinardi JR, et al. Eur J Endocrinol. 157:245, 2007.

Pediatric Endocrinology

**EUROPEAN REGISTRIES FOR RARE ENDOCRINE CONDITIONS (EURORECA): RESULTS FROM THE PLATFORM FOR E-REPORTING OF RARE ENDOCRINE CONDITIONS (E-REC)**

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**EUROPEAN REGISTRIES FOR RARE ENDOCRINE CONDITIONS (EURORECA): RESULTS FROM THE PLATFORM FOR E-REPORTING OF RARE ENDOCRINE CONDITIONS (E-REC)**

Background: Somatrogon (hGH-CTP) is a long acting recombinant human growth hormone (rhGH; somatropin) in development for once weekly treatment of children with growth hormone deficiency (GHD). Somatrogon contains the amino acid sequence of hGH and three copies of the carboxy-terminal peptide (CTP) derived from human chorionic gonadotropin. A 12 month phase 2 trial of once weekly Somatrogon vs daily Genotropin in children with GHD demonstrated that 0.66 mg/kg/wk of Somatrogon had a similar benefit - risk profile as 0.24 mg/kg/wk of Genotropin. The open label extension of this phase 2 study has generated an additional 5 years of longitudinal efficacy.

**SUN-070**

Background: Somatrogon (hGH-CTP) is a long acting recombinant human growth hormone (rhGH; somatropin) in development for once weekly treatment of children with growth hormone deficiency (GHD). Somatrogon contains the amino acid sequence of hGH and three copies of the carboxy-terminal peptide (CTP) derived from human choric gonadotropin. A 12 month phase 2 trial of once weekly Somatrogon vs daily Genotropin in children with GHD demonstrated that 0.66 mg/kg/wk of Somatrogon had a similar benefit - risk profile as 0.24 mg/kg/wk of Genotropin. The open label extension of this phase 2 study has generated an additional 5 years of longitudinal efficacy.

**RESULTS**

On a monthly basis over 1 year, a median of 14 (range 11, 21) paediatric centres and 13 (11, 25) adult centres actively reported cases. A median of 53 (22, 80) paediatric cases and 96 (42, 250) adult cases were reported monthly. Amongst paediatric cases, conditions within the Sex Development and Maturation (SDM) theme were most commonly reported comprising 36% of all reported conditions, with XY, DSD being the most commonly reported condition (24% of cases). Amongst adults, Pituitary and Thyroid conditions were most commonly reported, 34% and 26% of all conditions, respectively. Amongst conditions within the Pituitary group, pituitary adenoma was the most commonly reported condition (74% of cases) and non-metastatic thyroid carcinoma was the most commonly reported condition (95% of cases) amongst the Thyroid group. In children, the median number of cases reported per centre was 21 (9, 32) for conditions affecting SDM. In adults, a median of 37 (6, 75) Pituitary and 22 (6, 80) Thyroid cases were reported per centre. Conclusion e-REC is a simple, yet effective, platform that can be used to capture information on new encounters with patients with several rare conditions and can be adapted to serve the needs of other discrete networks that are interested in understanding the occurrence of rare conditions.

**OR10-06**

Background: Somatrogon (hGH-CTP) is a long acting recombinant human growth hormone (rhGH; somatropin) in development for once weekly treatment of children with growth hormone deficiency (GHD). Somatrogon contains the amino acid sequence of hGH and three copies of the carboxy-terminal peptide (CTP) derived from human chorionic gonadotropin. A 12 month phase 2 trial of once weekly Somatrogon vs daily Genotropin in children with GHD demonstrated that 0.66 mg/kg/wk of Somatrogon had a similar benefit - risk profile as 0.24 mg/kg/wk of Genotropin. The open label extension of this phase 2 study has generated an additional 5 years of longitudinal efficacy.

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and safety data with this dose. This report summarizes top line results from a pivotal phase 3 global trial (ClinicalTrials.gov: NCT02968004) designed to investigate the non-inferiority of once weekly Somatrogon hGH-CTP compared to daily hGH after 12 months in treatment-naive prepubertal children with GHD. Methods: The Phase 3 trial enrolled 224 subjects who were randomized in a 1:1 ratio to receive either once weekly Somatrogon hGH-CTP (0.66 mg/kg) or once daily Genotropin (0.24 mg/kg/wk) for 12 months. Randomization was stratified by geographic region, peak GH level and age. The primary endpoint of the study was height velocity (HV) at month 12; secondary endpoints included HV at month 6, change in height SDS at month 6 and 12, IGF-1 and IGFI SDS, immunogenicity, and safety. Results: At baseline, the mean (SD) age and height SDS of the somatrogon (N=109, 75.2% male) and Genotropin (N=115, 68.7% male) groups were 7.83 (2.66) and -2.94 (1.29) and 7.61 (2.37) and -2.78 (1.27), respectively. One subject in each group discontinued during the 12 month study, and 95% of the completers continued into an open-label extension study. At month 12, mean HV was 10.12 cm/yr in the Somatrogon group and 9.78 cm/yr in the Genotropin group, with the treatment difference of 0.33 cm/year favoring Somatrogon. The lower bound of the two-sided 95% confidence interval of the treatment difference was -0.39, which was higher than the pre-established non-inferiority margin and demonstrated non-inferiority of once weekly somatrogon vs daily Genotropin therapy. Height velocity at month 6 (10.60 cm/yr vs 10.04 cm/yr), change in height SDS at months 6 (0.54 vs 0.48) and 12 (0.92 vs 0.87) were likewise numerically higher in the Somatrogon-treated cohort. The majority of adverse events were mild to moderate in severity (somatrogon: 78.9%, Genotropin: 79.1%) and, overall, weekly somatrogon was generally well-tolerated and comparable to daily Genotropin. Conclusion: Top-line results from the pivotal phase 3 trial demonstrate that Somatrogon (hGH-CTP) given once weekly by sc injection is non-inferior to Genotropin (hGH) given once daily and that once weekly somatrogon administration was generally well-tolerated in patients with pGHD.

Bone and Mineral Metabolism
CLINICAL ASPECTS OF OSTEOPOROSIS AND VITAMIN D ACTION
A Study on the Oral Vitamin D Supplementary Treatment of Korean Children and Adolescents
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MON-383
Purpose: Between 2017 and 2018, the prevalence rate of vitamin D deficiency (VDD) among children and adolescents in Korea (single institution) was 68.4 percent (59.6 percent for males and 72.5 percent for females). However, effective vitamin D supplements are not consistent in literature. We tried to find out about the dosage and the duration of the administration. Methods: The study was conducted on 2,770 children aged 0-18 who tested serum vitamin D concentrations for outpatients and inpatients at our hospitals from August 2017 to July 2019. One group was treated with maintenance doses and the other group was treated with maintenance doses after oral vitamin D 2000 IU/d for six weeks. The maintenance dose was 400 IU/d before puberty and 1000 IU/d after puberty. Results: There was a significant correlation between serum 25(OH) vitamin D concentration and gender, age, season, weight SDS and BMI SDS (p=0.000, p=0.000, p=0.000, p=0.000, p=0.002, respectively). After 6 months of oral Vitamin D treatment, serum 25 (OH) Vitamin D concentration was increased in both groups (p=0.000, p=0.000, respectively). In a group treated with maintenance doses after oral vitamin D 2000 IU/d for six weeks, it was found a higher rate of change to vitamin D sufficiency (p<0.000). Conclusions: The prevalence rate of VDD increases in female, older age, overweight and winter. The serum 25 (OH) vitamin D concentration increased in both groups after 6 months of treatment. In VDD children, it seemed appropriate to take an oral Vitamin D 2000 IU/day for 6 weeks before maintenance treatment according to the current guideline treatment.

Pediatric Endocrinology
PEDIATRIC PUBERTY, TRANSGENDER HEALTH, AND GENERAL ENDOCRINE
Prenatal Exposure to Artificial Sweeteners
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SUN-055
Introduction: In adults, epidemiologic studies consistently show negative health outcomes (e.g. insulin resistance, stroke) related to artificial (or non-nutritive) sweetener (NNS) intake. In children, NNS sweetened beverage consumption is associated with higher total energy and sugar intake. In infants, we documented the immediate appearance of NNS in breast milk after mothers consume diet soda. A positive association between prenatal NNS exposure and higher BMI at 1 year of life has been observed in infants whose mothers routinely consumed NNS during pregnancy. In mice, we recently reported marked changes in intestinal microbiome and hepatic detoxification pathways of pups that had been exposed to NNS via their mothers’ intake during pregnancy and lactation. Thus, we conducted a pilot project to determine whether there is direct evidence for prenatal NNS exposure in humans. In future studies, we will investigate effects on health outcomes.

Methods: Concentrations of 3 NNS (acesulfame-potassium (ace-K), sucralose and saccharin) were measured with liquid chromatography-mass spectrometry in cord blood samples (n=15) and amniotic fluid samples (n=13). Aspartame cannot be measured because of its prompt metabolism into aspartic acid and phenylalanine. The cord blood samples were obtained from offspring of women enrolled in a sickle cell clinical trial at the NIH, while the amniotic fluid samples had been obtained for clinical purposes during the 3rd trimester. No dietary information was available other