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 IGF-I 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

Seung Yang, MD,PhD.
Hanyang University College of Medicine, Seoul, Korea, Republic of.

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

Brianna C. Halasa, BA[1], Allison Sylvetsky, PhD[2], Ellen M. Conway, BS[1], Peter J. Walter, PhD[1], Hongyi Cai, PhD[1], Mary F. Walter, PhD[1], Eileen Schouppe, MS[1], Lisa Hui, PhD[3], Kristina I. Rother, MHSc, MD[1].
[1]NATIONAL INSTITUTES OF HEALTH, Bethesda, MD, USA, [2]George Washington University, Washington, DC, USA, [3]University of Melbourne, Melbourne, Australia.

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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

than 2 of 13 women were not in the fasting state when undergoing amniocentesis.

Results: In the cord blood samples, ace-K and saccharin were present in 12/15 (80%) samples. None of the samples contained sucralose. In the 13 amniotic fluid samples, 10 (77%) samples contained at least one sweetener. One sample was positive for all 3 sweeteners. Maximum concentrations in cord blood were 6.5 ng/mL for ace-K and 2.7 ng/mL for saccharin, while maximum concentrations in amniotic fluid were 78.9 ng/mL for ace-K, 55.9 ng/mL for saccharin, and 30.6 ng/mL for sucralose (non-fasting sample). Most women were in the fasting state before undergoing amniocentesis or giving birth, thus NNS peak concentrations could not be determined in this pilot study.

Discussion and Conclusion: 80% of cord blood samples (babies' blood) and 77% of amniotic fluid samples (reflecting babies' direct gastrointestinal/lung exposure) contained ace-K, saccharin and/or sucralose. We speculate that NNS exposure may influence in utero growth and development, e.g. sweet taste preference and metabolic pathways. Prospective studies are necessary to test these hypotheses. Results will determine whether current recommendations (or lack thereof) regarding NNS intake during pregnancy and lactation need to be revised.

Neuroendocrinology and Pituitary

PITUITARY TUMORS II

Prolactin as a Surrogate Marker to Predict Long Term Postoperative Hypopituitarism After Transsphenoidal Resection of Pituitary Adenomas

Massiell German, MD, Devaprabu Abraham, MD, William Couldwell, MD, PhD, Debra L. Simmons, MD, MS, Anu Sharma, MD.

University of Utah School of Medicine, Salt Lake City, UT, USA.

MON-304

Transsphenoidal surgery (TSS) is the first line treatment for pituitary adenoma. A well-known complication of TSS is hypopituitarism with a reported risk of 5-25% after resection of pituitary adenomas. A decrease in postoperative prolactin concentration was shown to be associated with postoperative hypopituitarism in a previous report. We hypothesized that in addition to clinical factors (preoperative hypofunction and adenoma size), biochemical factors (change in prolactin concentration and immediate postoperative hypofunction) can aid in predicting long term hypopituitarism as defined as ≥1 biochemically confirmed hypofunctioning pituitary axes 3 years after resection. A retrospective analysis of all patients undergoing TSS for both functioning and non-functioning pituitary adenomas at a tertiary center from January 2013 through December 2015 was performed. Prolactinomas were excluded. Of the 75 patients included, 21.3% (n=16) had at least one pituitary axis requiring replacement at 3 years post operatively. Mean age at presentation was 55 ± 16 years, 55% were female and 81% were Caucasian. Mean adenoma size was no different between normal pituitary function and hypopituitary groups (24.0 ± 11.9 mm versus 25.3 ± 10, p=0.7). Factors associated with long term hypopituitarism were older age (mean age 64 ± 4 years versus 53 ± 2 years, p = 0.02), preoperative secondary adrenal insufficiency (AM cortisol 6.4 ± 3.7 vs 12.0 ± 6.5 μg/dL; p = 0.03), preoperative secondary hypothyroidism (0.8 ± 0.2 vs 12.0 ± 6.5 ng/dL; p < 0.01), low immediate postoperative cortisol (5.3±3.1 vs 26.1±18.3 μg/d; p<0.01), and persistence of adrenal insufficiency (10.7% vs 2.7%; p<0.01) and secondary hypothyroidism (13.3% vs 5.3%; p<0.01) at 3 months. Change in prolactin concentration from preoperative to postoperative day 1-7 was not significantly different between groups (p=0.09) due to the higher variability in the hypopituitary group (median 0.2 ng/mL, IQR -0.5 - 0.8 ng/mL) compared to the normal pituitary function group (median 0.7 ng/mL, IQR 0.5-0.8 ng/mL). Adenoma size, optic chiasm and cavernous sinus involvement were not associated with long term hypopituitarism. In patients who developed postoperative hypopituitarism, there was a higher frequency of adenoma persistence or recurrence (20% vs 47%). There was a high rate of patients lost to follow up (56%). Older age, the presence of preoperative secondary adrenal insufficiency and hypothyroidism, and low day 1-7 postoperative cortisol concentration are factors that can be used to deem a patient high risk for future hypopituitarism. These patients should have close follow up with continued screening postoperatively. Contrary to prior reports, adenoma size and parasellar involvement were not associated which may be suggestive of surgical expertise. Prolactin concentrations proved not to be a good surrogate marker to predict long term hypopituitarism.

Reproductive Endocrinology

SEX, GENDER, AND HORMONES

Sexual Desire Changes in Transgender Individuals upon Initiation of Hormone Treatment; Results from the Longitudinal ENIGI Study

Justine Defreyne, MD[1], Els Elaut, PhD[1], Baudewijntje Kreukels, MD, PhD[2], Alessandra Daphne Fisher, MD, PhD[3], Giovanni Castellini, MD, PhD[4], Annemieke Staphorsius, Master[2], Martin Den Heijer, MD, PhD[2], Gunter Heylens, MD, PhD[1], Guy G. T'Sjoen, MD,PHD[5].

[1]Ghent University Hospital, Ghent, Belgium, [2]Amsterdam University Medical Center, Amsterdam, Netherlands, [3]Department of Experimental, Clinical and Biomedical Sciences, FIRENZE, Italy, [4]University of Florence, Florence, Italy, [5]University Ghent, Gent, Belgium.

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Introduction: Several steps in the transitioning process may affect sexual desire in transgender people. This is often underexposed by those providing gender affirming care. Testosterone therapy in transgender men (TM) generally leads to increasing frequency of desire, masturbation, sexual fantasies and arousal. Studies in transgender women (TW) are inconclusive: some report an increase in the prevalence of hypoactive sexual desire after initiation of hormone therapy, whereas others have shown a positive impact of hormonal therapy on sexual quality of life. The current study prospectively assesses sexual desire during the first three years of hormonal therapy (HT) in transgender people. Methods: This prospective cohort study was part of the European Network for the Investigation of Gender Incongruence (ENIGI). Sexual desire was prospectively assessed in 766 participants (401 TW, 364 TM) by Sexual