NEW PRODUCT NEWSLETTER

An overview of new products launched in 1st Quarter, 2026

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Ideas for healthcare

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Abstract

Effect of tirzepatide treatment on patient-reported outcomes among SURMOUNT-OSA participants with obstructive sleep apnea and obesity

Dr. Chisom Kanu,

Eli Lilly and Company, Indianapolis, IN, USA.

In the phase 3 SURMOUNT-OSA trials, tirzepatide treatment significantly reduced the apnea-hypopnea index (AHI) among people with moderate-to-severe obstructive sleep apnea (OSA) and obesity. We evaluated effects of tirzepatide treatment on sleep disturbance, sleep-related impairment, functioning, health-related quality of life (HRQoL), and OSA symptoms in SURMOUNT-OSA participants. Methods: SURMOUNT-OSA consisted of two randomized, placebo-controlled trials of tirzepatide (10 mg or 15 mg) or placebo for 52 weeks in participants with moderate-to-severe OSA and obesity. For participants using PAP (Study 2), PAP was withdrawn prior to assessments of polysomnography and patient-reported outcome measures (PROMs). Prespecified PROM endpoints were from baseline to Week 52. Changes in sleep-related impairment, sleep disturbance, excessive daytime sleepiness, functioning, and HRQoL were assessed using analysis of covariance. Categorical shifts in OSA symptom severity were described. Results: At Week 52, compared with placebo, tirzepatide-treated participants reported significantly improved Patient-Reported Outcomes Measurement Information System (PROMIS) Short-Form Sleep related Impairment 8a scores, PROMIS Short-Form v1.0 Sleep Disturbance 8b scores, Functional Outcomes of Sleep Questionnaire Activity Level scores, EQ-5D-5L scores, and most domains of the Short-Form 36 Health Survey, Version 2. Tirzepatide treatment was also associated with greater improvements in Patient Global Impression of Status and Patient Global Impression of Change symptom scales compared with placebo. Additionally, Study 1 participants reported significant changes in Epworth Sleepiness Scale scores. Conclusion: Results indicate that in addition to objective outcomes of improved AHI, hypoxic burden associated with OSA, and cardiovascular risk factors, people with OSA reported benefits in symptoms, functioning, and HRQoL following tirzepatide treatment.

Reference: Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN, 46285, USA.

Abstract

Efficacy and safety of ferric citrate hydrate compared with sodium ferrous citrate in Japanese patients with iron deficiency anemia

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Japanese Society of Hematology.

Oral iron preparations are used as first-line treatment for iron deficiency anemia (IDA), but their gastrointestinal side effects prevent patients from appropriate adherence. We recently conducted a randomized, double-blind, phase 3 non-inferiority study to evaluate the efficacy and safety of two dosages of ferric citrate hydrate (FC) compared with sodium ferrous citrate (SF) in patients with IDA. FC at both 500 and 1000 mg/day was non-inferior to SF at 100 mg/day in terms of the change in the hemoglobin concentration at Week 7 from baseline. Logistic regression analysis suggested that the cumulative proportion of patients who achieved the target hemoglobin concentration (≥ 13.0 g/dL in male patients and ≥ 12.0 g/dL in female patients) at Week 7 was highest among those treated with FC at 1000 mg/day, followed by SF at 100 mg/day and FC at 500 mg/day. Both dosages of FC were well tolerated in patients with IDA. The incidences of nausea and vomiting were significantly lower in the FC treatment groups than in the SF group. In conclusion, FC has potential to be an oral iron preparation with sufficient efficacy for the treatment of IDA and a lower risk of nausea and vomiting.

Ref: International Journal of Hematology.

Abstract

Acute Effect of Topical Menthol on Chronic Pain in Slaughterhouse Workers with Carpal Tunnel Syndrome: Triple-Blind, Randomized Placebo-Controlled Trial

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Topical menthol gels are classified"topical analgesics" and are claimed to relieve minor aches and pains of the musculoskeletal system. In this study we investigate the acute effect of topical menthol on carpal tunnel syndrome (CTS). We screened 645 slaughterhouse workers and recruited 10 participants with CTS and chronic pain of the arm/hand who were randomly distributed into two groups to receive topical menthol (Bio freeze) or placebo (gel with a menthol scent) during the working day and 48 hours later the other treatment (crossover design). Participants rated arm/hand pain intensity during the last hour of work (scale 0–10) immediatelybefore1, 2, and 3hoursafterapplication.Furthermore, global rating of change (GROC)in arm/hand pain was assessed 3hours after application. Compared with placebo, pain intensity and GROC (= 0.026and= 0.044, resp.).Pain intensity of the arm/hand decreased by −1.2 (CI 95%: −1.7 to −0.6) following topical menthol compared with placebo, corresponding to a moderate effect size of 0.63.Inconclusion, topical menthol acutely reduces pain intensity during the working day in slaughterhouse workers with CTS and should be considered as an effective non systemic alternative to regular analgesics in the workplace management of chronic and neuropathic pain.

Ref: Rehabilitation Research and Practice.

Abstract

Safety and effectiveness of fixed dose combination of amitriptyline and chlordiazepoxide (Libotryp® and Libotryp-DS®) in the management of depression with co-morbid anxiety: protocol and design of a prospective, single arm, multi-centric, PMS study

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Depression and anxiety are most disabling psychiatric conditions and add significantly to global health related burden. Lifetime prevalence of major depression and anxiety disorders are very common and many times they can co-exist in the same time frame. The outcomes are poorer in such situations and compliance to medication is key to improve prognosis. A combination of tricyclic antidepressants and benzodiazepine is more practical in terms of compliance, and advantageous than that of a single class of drugs for the management of depression with co-morbid anxiety. This study will evaluate the safety and effectiveness of a fixed dose combination of amitriptyline and chlordiazepoxide as a part of post marketing surveillance. This is a prospective, single arm, multicentre, study which enrols patients who have been initiated with FDC of amitriptyline and chlordiazepoxidetablets for the treatment of depression with co-morbid anxiety. A total of 375 patients will be enrolled and clinical assessments for safety will be done at follow up visits; assessments for effectiveness will be done using Hamilton Depression Rating Scale (HDRS or HAM-D) and Hamilton Anxiety Rating Scale (HARS or HAM-This study will provide more evidence on safety and usefulness of FDC of amitriptyline and chlordiazepoxide for the treatment of depression with co-morbid anxiety from Indian context.

Reference: Yadav SKYet al. Int J Clin Trials. 2022Aug;9(3):221-226

Abstract

Evaluation of dietary Pancreatin as an exogenous enzyme on growth performance, gene expression, immunological responses, serum immunoglobins, and intestinal morphology in cockerels

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The current study evaluated the inclusion of Pancreatin enzyme on growth performance, intestinal morphology, endogenous enzyme activity and immunological responses in cockerels. A total of 480 d-old-Hy-line cockerels were randomly divided into 5 treatments, with 6 replicates, 16 birds per cage.Birds were given a standard corn-soybean-based (CD) starter and grower diet. Exogenous Pancreatin enzyme was supplemented at 0: 250; 500; 750, and 1000 mg/kg. Results demonstrated that Pancreatin supplementation did not affect (P>0.05) the growth performance and duodenal enzyme activity of birds. However, the addition of Pancreatin enzyme at 500 mg/kg increased (P<0.05) jejunal villus height at 42 d; duodenal crypt depth and jejunal crypt depth at 70 d. Pancreatin supplementation except 1000 mg/kg increased (P<0.05) serum IgM but not IgA and IgG. Furthermore, Pancreatin supplementation had the potential to decrease jejunal pH, spleen gene expression, and antibodies titers against NDV. In conclusion, Pancreatin enzyme inclusion had no effect on cockerels' growth performance despite the variation found on the gut morphology. Pancreatin enzyme at intermediary amounts (500 and 750 mg/kg) showed a satisfactory serum immunoglobulin result but had the potential to modulate differently on the antibody titers against NDV and gene expression.

Ref: Journal of Applied Animal Research.

Abstract

Pharmacokinetic/Pharmacodynamic Profile of Voriconazole

Dr. Ursula Theuretzbacher,

Founder and CEO of Center for Anti-Infective Agents (CEFAIA), Vienna, Austria.

Voriconazole is the first available second-generation triazole with potent activity against a broad spectrum of clinically significant fungal pathogens, including Aspergillus, Candida, Cryptococcus neoformans, and some less common moulds. Voriconazole is rapidly absorbed within 2 hours after oral administration and the oral bioavailability is over 90%, thus allowing switching between oral and intravenous formulations when clinically appropriate. Voriconazole shows nonlinear pharmacokinetics due to its capacity-limited elimination, and its pharmacokinetics are therefore dependent upon the administered dose. With increasing dose, voriconazole shows a superproportional increase in area under the plasma concentration-time curve (AUC). In doses used in children (age < 12 years) voriconazole pharmacokinetics appear to be linear. Steady-state plasma concentrations are reached approximately 5 days after both intravenous and oral administration; however, steady state is reached within 24 hours with voriconazole administered as an intravenous loading dose. The volume of distribution of voriconazole is 2–4.6 L/kg, suggesting extensive distribution into extracellular and intracellular compartments. Voriconazole was measured in tissue samples of brain, liver, kidney, heart, lung as well as cerebrospinal fluid. The plasma protein binding is about 60% and independent of dose or plasma concentrations. Clearance is hepatic via N-oxidation by the hepatic cytochrome P450 (CYP) isoenzymes, CYP2C19, CYP2C9 and CYP3A4. The elimination half-life of voriconazole is approximately 6 hours, and approximately 80% of the total dose is recovered in the urine, almost completely as metabolites. As with other azole drugs, the potential for drug interactions is considerable. Voriconazole shows time-dependent fungistatic activity against Candida species and time-dependent slow fungicidal activity against Aspergillus species. A short post-antifungal effect of voriconazole is evident only for Aspergillus species. The predictive pharmacokinetic/pharmacodynamic parameter for voriconazole treatment efficacy in Candida infections is the free drug AUC from 0 to 24 hour : minimum inhibitory concentration ratio.

Reference: Clin Pharmacokinet 45, 649–663 (2006)

Abstract

Fusidic acid in dermatology

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Fusidic acid is an antibiotic that belongs to a group of its own, the fusidanes. The molecule has a steroid-like structure but does not possess any steroid activity. The structure is thought to be responsible for the steroid-like high penetration, and for the fact that no cross-resistance or crossallergy has been seen with other antibiotics in routine clinical use. The anti-microbial activity of fusidic acid is specifically aimed at the most common skin pathogens, including Staphylococcus aureus, towards which it is one of the most potent antibiotics. The place of fusidic acid in dermatology is in the treatment of mild to moderately severe skin and soft-tissue infections, e.g. impetigo, folicullitis, erythrasma, furunculosis, abscesses and infected traumatic wounds, whereas it is of less use in conditions such as hidradenitis suppurativa, chronic leg ulcers, burns and pressure sores. The topical combinations of fusidic acid with either betamethasone or hydrocortisone are extremely useful in the treatment of atopic dermatitis/eczema whenever staphylococcal/secondary infection is suspected, and in more persistent cases of eczema where staphylococcal superantigen may be playing an important exacerbating role.

Reference: British Journal of Dermatology, Volume 139.

Abstract

Carisoprodol Single and Multiple Dose PK-PD. Part II: Pharmacodynamics Evaluation Method for Central Muscle Relaxants. Double-Blind Placebo-Controlled Clinical Trial in Healthy Volunteer

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Centrally acting skeletal muscle relaxants (CMR) such as carisoprodol are used to treat acute, painful musculoskeletal conditions, though its precise mode of action has not been charac terized. A double-blinded, placebo-controlled, randomized clinical trial was designed to evaluate the pharmacokinetics–pharmacodynamics (PKPD) of CMR after single (350 mg), double (70 0 mg), and multiple doses (up to 350 mg/8 h, 14 days) of carisoprodol. Muscular (Electromyogram–EMG, Carisoprodol Single and Multiple Dose PK-PD. Part II: Pharmacodynamics Evaluation Method for Central Muscle Relaxants. MDPI stays neutral with regard to jurisdictional claims in published maps and institutional affil iations. Copyright: © 2022 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). muscular strength dynamometry), central (sedation), and tolerability (psychomotor activity test, adverse events) parameters, as well as withdrawal symptoms, were evaluated. Thirteen healthy volunteers were enrolled. No evidence of direct muscle relaxation was evidenced, but some differences on sedation were evidenced throughout the study, suggesting that CMRs act, at least partly, through sedation. Most significant differences were detected at 1.5 h after dosing. The effect on psychomotor impairment was variable, most prominently after 1.5 h, too, suggesting that it is produced by carisoprodol rather than by meprobamate. No withdrawal symptoms were detected, so the risk of dependence following maximum doses and duration of treatment recommended, and under medical supervision, should be low.

Abstract

Pharmacokinetics and Safety of 0.5% Ivermectin Lotion for Head Louse Infestations

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The safety of a novel 0.5% ivermectin lotion (IVL) and potential for ivermectin absorption after application was investigated in an open-label study in young children, and a human repeat insult patch test (HRIPT) and cumulative irritation test (CIT) assessed any potential for cumulative dermal irritation and contact sensitization. In the pharmacokinetic and safety study, 30 head louse–infested children ages 6 months to 3 years received a 10-minute application of IVL on day 1. Blood was collected before application; 0.5, 1, and 6 hours after rinsing; and on days 2 and 8. Samples from 20 subjects were assayed for ivermectin (test sensitivity 0.05 ng/mL). Liver panel and complete blood counts were completed for all subjects. For the HRIPT/CIT, occlusive patches containing IVL or vehicle control lotion (CL) were repeatedly applied to 220 healthy adult subjects to assess contact sensitization; for cumulative dermal irritation testing, additional patches with normal saline and sodium dodecyl sulfate (SDS) were applied to 36 subjects. In the open-label study, all detected ivermectin plasma concentrations were <1 ng/mL. No safety signals emerged, and treatment was well tolerated. In the HRIPT/CIT, IVL was significantly less irritating than normal saline and SDS, with no evidence of dermal irritation or sensitization in human skin. IVL was safe when applied topically, absorption was de minimus, there was no evidence of irritation or sensitization from repeated exposures, and results support the safety of topical IVL use in children as young as 6 months.

Reference: Pediatric Dermatology Vol. 30 No. 3 323–328, 2013

Abstract

Safety and Performance of Narhinel 0.9% Sodium Chloride Monodose and Otrisal 0.74% Sodium Chloride Monodose Nasal Saline Solutions and Nasal Aspirators in Real-World Settings: Postmarket Clinical Follow-up Study Results

Mathieu M. Albasser, PhD, MSc, BSc,

GSK Consumer Healthcare SARL, a Haleon company, Nyon, Switzerland.

Blocked or stuffy nose is a common and bothersome symptom of colds, particularly for young children who are unable to clear their noses on their own. Nasal saline solutions and nasal aspirators are designed to gently cleanse and remove blocking nasal secretions. To assess the safety and performance of 2 monodose isotonic saline solutions (Narhinel 0.9% and Otrisal 0.74% sodium chloride; GSK Consumer Healthcare SARL, a Haleon company, Nyon, Switzer- land) and 2 nasal aspirators with disposable hard- and soft-nozzle refills used as a standalone or combi- nation treatment. We conducted 2 observational, online questionnaire-based, postmarket clinical follow-up studies in Europeans who had used any of the devices ≥1 time in the past 6 months. Coprimary objectives were to confirm the safety and performance of the saline solutions (Narhinel and Otrisal, Study 1) and nasal aspirators (with hard- and soft-nozzle refills, Study 2). Safety was assessed via the proportion of patients reporting adverse events and/or device malfunctions while using the devices within the previous 6 months and performance was assessed by satisfaction rated on a 5-point scale, with "satisfied" and "very satisfied" being the highest performance ratings. A total of 1136 (Study 1) and 1237 (Study 2) questionnaires were initiated by volunteer partic- ipants. Less than 2% of participants reported adverse events for any evaluated product in the previous 6 months. Most participants were "satisfied" or "very satisfied" with the devices for their intended use, with 78% to 91% of participants in the Narhinel arm, 73%–94% in the Otrisal arm, 71% to 95% in the soft-nozzle arm, and 71% to 80% in the hard-nozzle arm giving these ratings. These data support the safety and performance of 2 monodose saline solutions (Narhinel and Otrisal) for nasal cleansing, nasal moisturization, and/or loosening nasal secretions, and of nasal aspirators (with hard- and soft-nozzle refills) for clearing a blocked nose and removing nasal secretions.

Abstract

Apply evidence-based guidelines and clinical recommendations for using indomethacin in specific patient populations, including pediatric, geriatric, and pregnant individuals

Akul Munjal,

Tanta University School of Medicine, Georgia.

Indomethacin is a potent nonsteroidal anti-inflammatory drug with broad applications. The drug inhibits prostaglandin synthesis produced by cyclooxygenase enzymes, which are critical mediators of inflammation, fever, and pain. Indomethacin is approved by the US Food and Drug Administration (FDA) to manage acute pain, rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, bursitis, gouty arthritis, and patent ductus arteriosus. Clinicians often use indomethacin as a supportive treatment within a medication regimen. This activity focuses on the indications, contraindications, and administration methods of indomethacin as a valuable therapeutic agent, as well as its key factors, such as off-label uses, dosing, pharmacokinetics, monitoring, and relevant interactions. This activity underscores the crucial role of inter professional healthcare teams in monitoring indomethacin therapy by tailoring treatment plans to individual patient needs depending on pain acuity, making informed decisions, and optimizing dosage regimens while minimizing adverse reactions. This evidence-based approach improves patient outcomes in inflammatory conditions treated with indomethacin.

Abstract

Efficacy and safety of sitagliptin and metformin as initial combination therapy and as monotherapy over 2 years in patients with type 2 diabetes

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To assess the 104-week efficacy and safety of sitagliptin and metformin as initial combination therapy and as monotherapy in patients with type 2 diabetes and inadequate glycaemic control (HbA 1c 7.5–11%) on diet and exercise. This study was a 50-week, double-blind extension of a 54-week, randomized, double-blind, factorial study of the initial combination of sitagliptin and metformin, metformin monotherapy and sitagliptin monotherapy (104 weeks total duration). Patients assigned to active therapy in the 54-week base study remained on those treatments in the extension. Sitagliptin 50 mg b.i.d. + metformin 1000 mg b.i.d.(higher dose combination), sitagliptin 50 mg b.i.d. + metformin 500 mg b.i.d. (lower dose combination), metformin 1000 mg b.i.d. (higherdose), metformin 500 mg b.i.d. (lower dose) and sitagliptin 100 mg q.d. Patients randomized to receive the sequence of placebo/metformin were switched, in a blinded manner, from placebo to metformin monotherapy uptitrated to 1000 mg b.i.d. beginning at week 24 and remained on higher dose metformin through the extension. Amongst patients who entered the extension study without having initiated glycaemic rescue therapy, least-squares mean changes in HbA 1c from baseline at week 104 were −1.7% (higher dose combination), −1.4% (lower dose combination), −1.3% (higher dose), −1.1%(lower dose) and −1.2% (sitagliptin). The proportions of patients with an HbA 1c <7% at week 104 were 60% (higher dose combination), 45%(lower dose combination), 45% (higher dose), 28% (lower dose) and 32% (sitagliptin). Fasting and post meal measures of glycaemic controland β-cell function improved in all groups, with glycaemic responses generally maintained over the 104-week treatment period. The incidence of hypoglycaemia was low across all groups. The incidences of gastrointestinal adverse experiences were generally lower in the sitagliptin group and similar between the metformin monotherapy and combination groups. Initial combination therapy with sitagliptin and metformin and monotherapy with either drug alone provided substantial and sustained glycaemic improvements and were well tolerated over 104 weeks in patients with type 2 diabetes.

Reference: Diabetes, Obesity and Metabolism 12: 442–451.

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Mohammad Abdul Momen Talukder
Director, Sales & Marketing

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