Medical News

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FDA Approves 'Gamechanger' Semaglutide for Weight Loss Source: Medscape Medical News Source:https://www.medscape.com/viewarticle/952441

The US Food and Drug Administration (FDA) has approved a 2.4 mg/week subcutaneous dose of the glucagon-like peptide-1 (GLP-1) receptor agonist semaglutide (Wegovy, Novo Nordisk) for weight loss.

Specifically, this drug format and dosage are approved as an adjunct to a reduced-calorie diet and increased physical activity to treat adults who have obesity (body mass index [BMI] ≥ 30 kg/m^2) or are overweight (BMI ≥27 kg/m^2) with at least one weight-related comorbidity.

Semaglutide "induces weight loss by reducing hunger, increasing feelings of fullness, and thereby helping people eat less and reduce their calorie intake," according to a company statement.

"Gamechanger" Drug Tested in STEP Clinical Trial Program

The favorable FDA ruling is based on results from the Semaglutide Treatment Effect in People With Obesity (STEP) program of four phase 3 clinical trials that tested the drug's safety and efficacy in more than 4500 adults with overweight or obesity.

The four 68-week trials of subcutaneous semaglutide 2.4 mg/week versus placebo were published in the New England Journal of Medicine (STEP 1), The Lancet (STEP 2), and JAMA (STEP 3, STEP 4) in February and March 2021.

As previously reported by Medscape Medical News, all trials were in adults with overweight or obesity: • STEP 1 was in 1961 adults. • STEP 2 was in 1210 adults who also had diabetes. • STEP 3 was in 611 adults, where those in the treatment group also underwent an intensive lifestyle intervention. • STEP 4 was in 803 adults who had reached a target dose of 2.4 mg semaglutide after a 20-week run-in (and the trial examined further weight-loss in the subsequent 48 weeks).

In the STEP 1, 2, and 4 trials of individuals with overweight and obesity, those in the semaglutide groups attained a 15% to 18% weight loss over 68 weeks.

The dosage was well-tolerated. The most common side effects were gastrointestinal, and they were transient and mild or moderate in severity.

A coauthor of the STEP 1 trial, Rachel Batterham, MBBS, PhD, of the Centre for Obesity Research at University College London, UK, said at the time of publication: "The findings of this study represent a major breakthrough for improving the health of people with obesity."

"No other drug has come close to producing this level of weight loss — this really is a gamechanger. For the first time, people can achieve through drugs what was only possible through weight-loss surgery," she added.

Lower-Dose Injectable and Pill Already Approved for Diabetes

Subcutaneous semaglutide at doses up to 1 mg/week (Ozempic, Novo Nordisk), which comes as prefilled pens at doses of 0.5 mg or 1.0 mg, is already approved for the treatment of type 2 diabetes.

The company is also applying for approval for a higher dose of semaglutide, 2 mg/week, for use in type 2 diabetes, and has just resubmitted its label expansion application to the FDA, after the agency issued a refusal to file letter in March. And in September 2019, the FDA approved oral semaglutide (Rybelsus, Novo Nordisk), in doses of 7 and 14 mg/day, to improve glycemic control in type 2 diabetes, making it the first GLP-1 receptor agonist available in tablet form.

CVOT and Oral Format Trials for Obesity on the Horizon

The ongoing Semaglutide Effects on Heart Disease and Stroke in Patients With Overweight or Obesity (SELECT) trial will shed light on cardiovascular outcomes after 2.5 to 5 years in patients with cardiovascular disease and overweight or obesity but without type 2 diabetes. Participants will receive semaglutide in doses up to a maximum of 2.4 mg/week, or placebo, as an adjunct to lifestyle recommendations focused on cardiovascular risk reduction. The study is expected to complete in 2023. And Novo Nordisk plans to initiate a global 68-week phase 3 trial in the second half of 2021 on the efficacy and safety of oral semaglutide 50 mg compared with placebo in 1000 people with obesity or overweight and comorbidities.

Novel SARS-CoV-2 variants partially resistant to infection- and vaccine-induced immunity, study finds Source: https://www.news-medical.net/ news/20210602/Novel-SARS-CoV-2-variants-exhibit-partial-resistance-to-infection-and-vaccination-induced-immunity-study-finds.aspx

A recent study conducted by a team of scientists in the

Netherlands and the USA has revealed that while severely affected hospitalized coronavirus disease 2019 (COVID-19) patients and vaccinated individuals are capable of neutralizing the B.1.1.7, B.1.351, and P.1 variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a significant proportion of non-hospitalized patients with less severe COVID-19 remain susceptible to these viral variants. A preprint version of the study is available on the medRxiv* server, while the article undergoes peer review.

Background

With 171.3 million confirmed COVID-19 cases and 3.5 million deaths, the COVID-19 pandemic has become the largest pandemic in modern history. The frequent emergence of novel SARS-CoV-2 variants is continuously putting the global population under serious threat. Because of significantly increased infectivity and immune evasion ability, the World Health Organization (WHO) has designated some viral variants as the Variants of Concern (VOCs).

Among recognized VOCs, B.1.1.7, B.1.351, and P.1 have been identified first in the UK, South Africa, and Brazil, respectively. Soon after their emergence, these variants have started spreading globally, and cases with these variants have been detected in 132, 82, and 52 countries, respectively.

The N501Y mutation in the spike receptor-binding domain (RBD) is the common feature in all three VOCs. This mutation is known to increase the RBD affinity for human angiotensin-converting enzyme 2 (ACE2), explaining the increased infectivity of these VOCs. In addition, the E484K mutation found in B.1.351 and P.1 variants is known to facilitate viral escape from antibody-mediated neutralization.

In the current study, the scientists have compared the immune escape abilities of B.1.1.7, B.1.351, and P.1 variants. Specifically, they have investigated whether these VOCs can escape neutralization by monoclonal therapeutic antibodies and polyclonal antibodies derived from COVID-19 patients and vaccinated individuals.

Popular Drug Does Not Alleviate Mild Covid-19 Symptoms, Study Finds

Source: Medical News https://www.medicalnewspk.com/popular-drug-does-not-alleviate-mild-covid-19-symptoms-study-finds/

Colombia: Ivermectin, a controversial anti-parasitic drug that has been touted as a potential Covid-19 treatment, does not speed recovery in people with mild cases of the disease, according to a randomized controlled trial published on Thursday in the journal JAMA.

Ivermectin is typically used to treat parasitic worms in both people and animals, but scientific evidence for its efficacy against the coronavirus is thin. Some studies have indicated that the drug can prevent several different viruses from replicating in cells. And last year, researchers in Australia found that high doses of ivermectin suppressed SARS-CoV-2, the virus that causes Covid-19, in cell cultures.

Such findings had spurred use of the drug against Covid-19, especially in Latin America.

"Ivermectin is currently being used widely," said Dr. Eduardo López-Medina, a doctor and researcher at the Center for Pediatric Infectious Diseases in Cali, Colombia, who led the new trial. "In many countries in the Americas and other parts of the world, it's part of the national guidelines of treating Covid."

But the drug has also proved divisive. While some scientists see potential, others suspect that effectively inhibiting the coronavirus may require extremely high, potentially unsafe doses. Health officials have also worried that people desperate for coronavirus treatments might take versions of the drug that have been formulated for pets. (It is commonly used to prevent heartworm in dogs.)

"There's been a lot of conflicting views on this, sometimes extreme conflicting views," said Dr. Carlos Chaccour, a researcher at the Barcelona Institute for Global Health who was not involved in the new study. "I think it has become another hydroxychloroquine."

But neither the proponents nor the critics have had much rigorous data to support their views. There are few well-controlled trials of the drug's effectiveness against Covid-19, although more are expected in the coming months. And treatment guidelines from the National Institutes of Health note that there is not enough evidence "to recommend either for or against" using the drug in Covid-19 patients.

In the new study, Dr. López-Medina and his colleagues randomly assigned more than 400 people who had recently developed mild Covid-19 symptoms to receive a five-day course of either ivermectin or a placebo. They found that Covid-19 symptoms lasted about 10 days, on average, among people who received the drug, compared with 12 days among those who received the placebo, a statistically insignificant difference.

The new trial adds much-needed clinical data to the debate over using the drug to treat Covid-19, said Dr. Regina Rabinovich, a global health researcher at Harvard's T.H. Chan School of Public Health, who was not involved in the study.

But she noted that the trial was relatively small and did not answer the most pressing clinical question, whether ivermectin can prevent severe disease or death. "Duration of symptoms may not be the most important

either clinical or public health parameter to look at," she said.

The researchers did find that seven patients in the placebo group deteriorated after enrolling in the trial, compared to four in the ivermectin group, but the numbers were too small to draw a meaningful conclusion.

"There was a small signal there, and it would be interesting to see if that signal that we saw is real or not," said Dr. López-Medina. "But that would have to be answered in a larger trial."

Dr. López-Medina also pointed out that the study population was relatively young and healthy, with an average age of 37 and few of the underlying conditions that can make Covid-19 more dangerous.

Bigger trials, which are currently underway, could provide more definitive answers, said Dr. Rabinovich, who noted that she was "totally neutral" on ivermectin's potential usefulness. "I just want data because there's such chaos in the field."

Scientists explore herbal treatment for COVID-19
Source: Medical Xpress

Source: https://medicalxpress.com/news/2021-06-scientists-explore-herbal-treatment-covid-.html

Credit: George Mason University

Could an over-the-counter health "shot" help fight COVID-19? George Mason University researchers think it just might.

Cell and Bioscience recently highlighted research led by Yuntao Wu and Ramin Hakami in which they examined the potential anti-coronavirus activities of an over-the-counter drink called Respiratory Detox Shot (RDS).

RDS is a remedy containing nine herbal ingredients traditionally used in Eastern medicine to manage lung diseases. The researchers reported that RDS inhibited the infection of target cells by SARS-CoV and SARS-CoV-2 pseudoviruses and by infectious wild-type SARS-CoV-2. Their results suggest that RDS might broadly inhibit respiratory viruses, such as influenza.

SARS-CoV is the viral pathogen causing severe acute respiratory syndrome (SARS), and its sister virus, SARS-CoV-2, is the pathogen that causes COVID-19. The COVID-19 global pandemic is a major focus of researchers around the world. While effective vaccines have been developed, there is still a need for developing effective treatments. In particular, new variants of the virus are continuously emerging, and some of these variants may make the vaccines less effective.

Ramin Hakami, an associate professor in Mason's School of Systems Biology and one of the authors of the study, said that the fact that RDS is a drinkable food supplement is helpful.

"If it proves effective in vivo, it should be a treatment for COVID-19 that is easy to administer," said Hakami, who also works at Mason's National Center for Biodefense and Infectious Diseases. "That's a big plus."

For their study, Hakami, Wu, and Mason researchers Brian Hetrick, Adeyemi A. Olanrewaju, Linda D. Chillin, Sijia He, and Deemah Debbagh worked with Dongyang Yu of Virongy LLC, Yuan-Chun Ma of Dr. Ma's Laboratories Inc., and Lewis A. Hoffman of the World Health Science Organization.

The team screened extracts from approximately 40 medicinal herbs using a SARS-CoV-2 pseudovirus and human lung cells. They also screened for possible anti-SARS-CoV-2 activity of RDS.

For the study, they pretreated cells with diluted RDS and then infected the cells in the presence of RDS for four to six hours. After infection, they cultured cells in the absence of RDS and then quantified the cells to determine if viral infection was inhibited at 48 and 72 hours.

Subsequently, the researchers used the Biomedical Research Lab on Mason's Science and Technology Campus to confirm the in vitro efficacy of RDS against infectious SARS-CoV-2 virus.

The study revealed that RDS contains very potent ingredients that can destroy the infectivity of SARS-CoV, SARS-CoV-2, and influenza A virus, even at very low dosages, said Wu, a professor in Mason's National Center for Biodefense and Infectious Diseases and a study co-author. In addition, the investigators have demonstrated that RDS is effective against the SARS-CoV-2 variants in vitro.

Hetrick, a Ph.D. student in biosciences working on the study, said that the discovery was a happy surprise for him. It would be great if there are safe and effective herbal drugs available for the management of COVID-19 in the future.

Hakami is currently conducting in vivo animal studies to build on the in vitro discovery that RDS may be used as a SARS-CoV-2 treatment. He is testing RDS using K18-hACE2 transgenic mice that will be infected with SARS-CoV-2. Depending on the results, Dejia Harmony, the sponsor of the above pre-clinical trial, may seek FDA approval to begin human clinical trials.

"This study points to the possibility of using a readily available, over-the-counter herbal beverage to provide protection against SARS-CoV-2 and influenza A infections," said Ali Andalibi, senior associate Dean in Mason's College of Science.

PSIM News

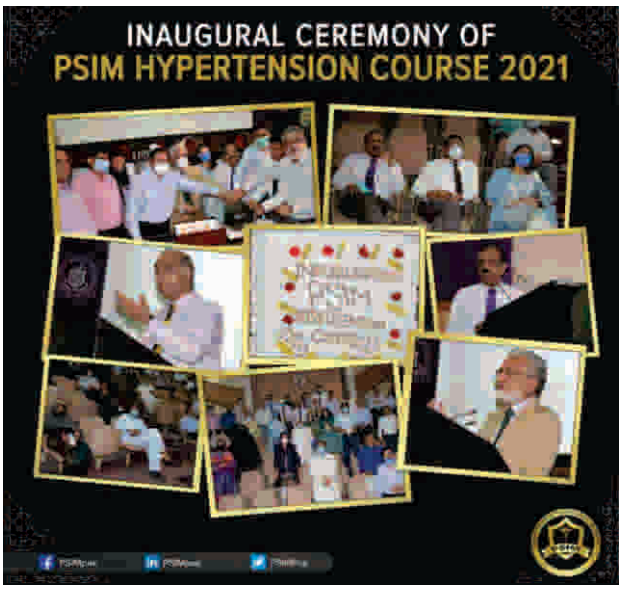
PSIM-international hypertension course 2021

Pakistan Society of Internal Medicine (PSIM), the prestigious organization of physicians of Pakistan has launched an international course of Hypertension. The course is conducted in collaboration with World Hypertension League, International Society of Hypertension, Pakistan Cardiac Society, Pakistan Hypertension League and University of Health Sciences. Weekly modules of the course spanning over 3 months will cover diversified topics encompassing A-Z of hypertension. Esteemed national & international speakers will impart knowledge to healthcare professionals on practical approaches to combat hypertension in their clinical practice. International faculty includes Prof. Daniel T Lackland, Prof. George Stergiou, Prof. Anthony Heagerty, Prof. Neil Poulter, Prof. Paul Leeson, Prof. Alta Schutte, Prof. Maciej Tomaszewaski, Prof. Fady Hanahshmouni and Prof. Xin Hua Zhang. National faculty includes Gen. Retd. Prof. Muhammad Aslam, Prof. Ejaz Vohra, Prof. Aizaz Mand Ahmed, Prof. Imran Hassan Khan, Prof. Khursheed Khan, Prof. Bikha Ram Devrajani, Prof. Muhammad Ishaq, Prof. Abdul Samad, Prof. Akbar Chaudhry, Prof. Haroon Aziz Babar, Prof. Munir Azhar, Dr. Moazzam Baig Mirza, Prof. Azhar Farouqi, Prof. Shahbaz Kureshi, Prof. Hafeez Chaudhry, Prof. Tahir Masood Ahmed, Prof. Masood Hameed Khan, Prof. Rauf Niazi, Prof. A. H. Amir, Prof. Muhammad Naeem Kasuri, Prof. Masood Sadiq, Prof. Amir Shaukat, Prof. Saulat Siddique, Prof. Hafeezullah, Prof. Aftab Mohsin and Prof. Jalil ud Daula. Prof. Javed Akram, president PSIM is the patron & Prof. Aziz-ur-Rehman is the course director. The organizing committee includes Prof. Tariq Wasim, Prof. Sajid Abaidullah, Prof. Sheikh Bilal Mohydin, Dr Somia Iqtadar, Dr Sami ullah Mumtaz, Mr. Asif Hussain & Mr. Kashif Riaz. More than 600 participants have registered for the course from all across Pakistan. Each module of the course consists of 2 state-of-the-art lectures with panelists' discussion, question answer sessions & pre & post test assessments for the participants. By now 6 out of 15 sessions are already completed.

Establishing First of its Kind Vitamin D Academy

Memorandum of Understanding (MoU) signing ceremony for the establishment of Pakistan's first Vitamin-D Academy took place in Governor House Punjab, Lahore on 1st April 2021 between University of Health Sciences (UHS), Lahore, Pakistan Society of Internal Medicine (PSIM) and national pharmaceutical firm PharmEvo Pvt. Ltd.

The ceremony was addressed by Governor of Punjab Mr. Chaudhary Sarwar, Prof. Dr. Javed Akram, Vice



Chancellor, University of Health Sciences (UHS), Dr. Somia Iqtadar General Secretary, PSIM, Mr. Haroon Qassim, Managing Director, PharmEvo, Mr. Syed Jamshed Ahmed. CEO, PharmEvo.

The patron of newly established Vitamin D Academy is Governor of Punjab Mr. Chaudhary Sarwar who stressed the condition should be given equal importance along with diabetes, hypertension and obesity in the country..

The academy was formed with the objective to train physicians and healthcare providers about the importance of vitamin D and spread awareness about its role in the prevention and treatment of disease. Further, guidelines on vitamin D supplementation and administration will be prepared in consultation with national and international health experts is the main agenda of the academy.

In about two months' time, Vitamin D Academy in collaboration of UHS, PSIM & PharmEvo has inaugurated first event for doctors in Luxus Grand Hotel, Lahore on 5th June to complete 1st module of Vitamin D course. The event went live on zoom to accommodate virtual participants across country. The lectures were delivered by Prof. Dr. Javed Akram, Dr. Somia Iqtadar & Prof. Dr. Dilawaiz Nadeem. Approx. 80 physical and 100 virtual participants attended the first module.

PSIM FOUNDATION

PSIM, the society of highly learned medical professionals took the initiative for the social development of underprivileged individuals, groups & communities. In order to support general health within the community, PSIM aimed to establish welfare dispensaries & free clinics all over the country under one roof of PSIM Foundation. It is being established at 49-Mozang road

Lahore & is near completion. It will provide free of cost medical services including consultation, diagnostics & medicine to the poor deserving patients. It will also promote & conduct research for the benefit of the poor patients' management. Prof Sajid Abaidullah is the first Chief Executive Officer of this foundation. The other directors/promoters are Prof Javed Akram, Dr Shehla Javed Akram, Prof Aziz-ur-Rehman, Prof Tariq Wasim, Prof Aftab Mohsin, Dr Somia Iqtadar, Dr Asma Kazi & Dr Sami Ullah Mumtaz. It will consist of free state of the art internal medicine clinic supported by rheumatology, ophthalmology, nephrology & physiotherapy & rehabilitation consolations. It will also include free laboratory as well as radiological diagnostic facilities.

The directors are very enthusiastic & thrilled to work for this noble cause only & only for the Allah's will by helping His ailing humanity. All of PSIM members & physicians may become the part of this noble cause by giving some free time for poor patients' free consultation or helping out their miseries. we pray Allah Almighty bless us with the courage, energy and wisdom to run this state-of-the-art centre for His poor ailing humanity forever.

PSIM USA chapter launch

PSIM launched the USA Chapter of Pakistan Society of Internal Medicine in April 2021. Dr. Samia Nawab Waseem is the first President of USA Chapter, PSIM. She has been the president of Association of Pakistani physicians of north America (APPNA) & King Edward Medical College Alumni Association of North America (KEMCAANA) year 2020. Dr Samia was very delighted after selection as president of USA chapter of this prestigious society. On launching ceremony, she said that that She found PSIM a great forum for research & academics for young physicians. She also said that it's a great opportunity for young physicians & researchers working in different positions in USA to contribute for this prestigious organization. She was anxious to introduce PSIM to APPNA & KEMCAANA. USA chapter is the 4th overseas chapter of PSIM after U.K, Europe & Middle East.