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A News letter on

CLINICAL PHARMA PRACTICE

An update of Clinical research and Drug information

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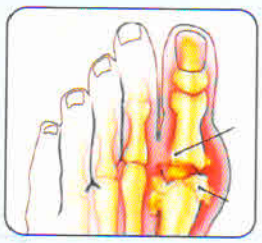
PHYSICIAN DESK

GOUTY ARTHRITIS



Gout is a type of arthritis that causes sudden joint inflammation, usually in one joint. Severe gout can sometimes affect many joints at once. This is known as polyarticular gout.

REASON FOR GOUT

The primary reason for gout is foods with high amounts of purine. Foods such as fish, seafood and shellfish, sardines, mussels, codfish, liver, beef kidney, brain, alcoholic beverages, sweetbreads considered high in purine

Gout is more common after surgery, trauma, and dehydration. Certain medications such as diuretics that raise the level of uric acid in the bloodstream are risks for gout. Surprisingly, medications that lower the level of uric acid in the bloodstream, such as allopurinol, can also initially cause a flare of gout. This is because anything that raises or lowers the uric acid level can cause a gout flare by causing uric acid crystals to deposit in a joint. Low-dose aspirin may precipitate gout attacks. The treatment of certain types of cancer can cause gout because of high levels of uric acid released when cells are destroyed. Degenerative arthritis also makes affected joints more likely to be the site of a gouty attack.

DIAGNOSIS

The most reliable method to diagnose gout is by demonstrating uric acid crystals in joint fluid that has been removed from an inflamed joint. Specially trained physicians, such as a rheumatologist or orthopedist, can carefully remove fluid from the joint. The fluid is then examined under a microscope to determine if uric acid crystals are present.

TREATMENT

Uric-acid-lowering medications are the primary treatment for gout. Uric-acid-lowering medications include allopurinol, febuxostat, probenecid, and pegloticase.

Colchicine and any of the NSAIDs (nonsteroidal anti-inflammatory drugs) such as indomethacin, diclofenac, ibuprofen, or naproxen sodium are frequently used as prophylactic medications to prevent gout flares during uric-acid lowering. Steroid medications, such as prednisone and methylprednisolone, also can be used during an acute gouty flare.

The recent definition of etoricoxib as an effective COX-2-selective inhibitor in acute gout has opened up a new therapeutic approach, but the cardiovascular safety of COX2 inhibitors remains under review. The establishment, in the past 2 years, of the evidence basis for oral glucocorticosteroid treatment of acute gout is also particularly significant, for example, for subjects with CKD. Specifically, prednisolone 35 mg daily for 5 days and naproxen 500 mg twice daily for 5 days have been demonstrated to be comparable in efficacy and tolerance in a recent trial of acute gout treatment. Prednisolone (6 doses of 30 mg over 5 days) was also comparable in efficacy to indomethacin and better tolerated in an acute gout trial.

CLINICAL RESEARCH

IMMUNOTHERAPY HERALDS 'NEW ERA' FOR CANCER TREATMENT

Immunotherapy in 19% of patients who received ipilimumab alone experienced a reduction in tumor size for a period of 2.5 months, the tumors of 58% of patients who received nivolumab plus ipilimumab reduced by at least a third for almost a year. At 1 year after treatment, the researchers found nivolumab almost doubled patient survival. Around 42% of patients who received nivolumab were alive after 1 year, compared with only 24% of patients who received chemotherapy. Nivolumab plus ipilimumab reduced tumor size by at least a third for almost 1 year.

N Engl J Med;June 3,2015

FDA ADVISORY PANEL APPROVES NOVEL CHOLESTEROL - LOWERING DRUG

Alirocumab (brand name Praluent) lowers LDL cholesterol by inhibiting PCSK9 (proprotein convertase subtilisin/kexin type 9) - a protein that impairs the liver's ability to remove cholesterol from the blood.The research has demonstrated that "alirocumab is well-tolerated and provides substantial reductions in LDL-C [LDL cholesterol] for a population of patients whose LDL-C is not adequately controlled with existing therapies."

Medicalnews.com, June 10, 2015

LATUDA (LURASIDONE HCI) IN FIRST PLACEBO-CONTROLLED TRIAL OF PATIENTS WITH MAJOR DEPRESSIVE DISORDER WITH MIXED FEATURES

Sunovion Pharmaceuticals Inc. has announced results from the first placebo-controlled study in adults with major depressive disorder (MDD) who presented with a limited number of associated manic symptoms (mixed features). This study demonstrated that Latuda® (lurasidone HCI) significantly reduced depressive symptoms in adults with MDD with mixed features when compared to placebo. Adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression) both as monotherapy and as adjunctive therapy with lithium or valproate, and for the treatment of adult patients with schizophrenia.

Medicalnews .com, May 21, 2015.

REGENERON AND SANOFI ANNOUNCE POSITIVE PIVOTAL PHASE 2B DUPILUMAB DATA IN ASTHMA

Patients treated with either 200 mg or 300 mg Q2W doses of dupilumab showed a greater than 8 percent improvement in forced expiratory volume over one second (FEV1, a standard measure of lung function) at Week 12 (p less than 0.001), in comparison to placebo, both in combination with (inhaled corticosteroids) ICS/LABA(Long acting beta agonist). Additionally, the 200 mg and 300 mg Q2W doses of dupilumab in combination with ICS/LABA showed 68 percent and 62 percent reductions, respectively.

Drugs.com, May 18, 2015

VACCINE CANDIDATE POTENTIALLY EFFECTIVE AGAINST EBOLA IN LARGE TRIAL IN GUINE

NewLink Genetics Corporation (NASDAQ:NLNK) announced that the international partnership studying the VSV-ZEBOV (Ebola) vaccine candidate in Guinea has released interim data suggesting that it is effective against Ebola in a large clinical trial. According to the announcement, the interim results suggest that the vaccine candidate demonstrates efficacy within about 10 days of administration to a person without the infection.

Drugs.com, July 31, 2015

STUDY: ELEVATED CARDIAC TROPONIN T TIED TO CVD RISK IN DIABETES

The risk of cardiovascular mortality, myocardial infarction or stroke was 85% higher among type 2 diabetes patients with stable ischemic heart disease who had elevations in cardiac troponin-T concentration than those with a normal cardiac troponin-T concentration, according to a study in the New England Journal of Medicine. The findings also revealed that bypass surgery or stenting didn't improve health outcomes or lower the troponin concentrations among patients with elevated troponin T.

Medscape, August 13, 2015

RECENTLY APPROVED DRUGS BY FDA

S. No.	BRAND NAME / COMPANY	MOLECULE NAME	INDICATIONS	APPROVED MONTH & YEAR
1.	Rexulti / Otsuka	Brexpiprazole	Depression and schizophrenia	July 2015
2.	Odomzo / Novartis	Sonidegib	Carcinoma	July 2015
3.	Daklinza / Bristol-Myers Squibb	Daclatasvir	Infectious Diseases	July 2015
4.	Praluent / Sanofi Aventis	Alirocumab	Cardiovascular disease	July 2015
5.	Kengreal / The Medicines	Cangrelor	Periprocedural thrombotic events	June 2015
6.	Stiolto Respimat / Boehringer Ingelheim	Tiotropium bromide and olodaterol	COPD	May 2015
7.	Viberzi / Actavis	Eluxadoline	Irritable bowel syndrome with diarrhea	May 2015
8.	Xifaxan / Salix Pharmaceuticals	Rifaximin	Irritable bowel syndrome with diarrhea	May 2015
9.	Kybella/Kythera Biopharma	Deoxycholic acid	Submental fat	April 2015
10.	Corlanor/Amgen	Ivabradine	chronic heart failure	April 2015

NEW DRUG PROFILE

EMPAGLIFLOZIN

Indication

It is a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosage and administration

- The recommended dose of empagliflozin is 10 mg once daily, taken in the morning, with or without food.
- Dose may be increased to 25 mg once daily.

Dosage forms and strengths

- Tablets: 10 mg, 25 mg

Contraindications

- Serious hypersensitivity reaction
- Severe renal impairment, end-stage renal disease, or dialysis.

Precautions

- Hypotension: Increased risk of hypotension in patients with renal impairment, the elderly, concomitant diuretic use
- Increased risk of renal impairment in elderly patients and those with moderate renal impairment
- Monitor renal function during therapy. More frequent monitoring is recommended in patients with eGFR below 60 mL / min / 1.73 m2 (5.2)
- Increased risk of hypoglycemia with insulin secretagogues or insulin
- Increased risk of Urinary tract infection

Adverse reactions

- Hypotension
- Hypoglycemia
- Impairment in Renal Function
- Urinary Tract Infections

Pregnancy category : C

GADOBUTROL

Indication

It is a gadolinium-based contrast agent indicated for intravenous use in diagnostic MRI in adults and children to detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the CNS.

Dosage and administration

- The recommended dose of Gadobutrol is 0.1 ml/kg body weight (0.1 mmol/kg), administered as an intravenous bolus injection at a flow rate of approximately 2 ml/second.
- Flush the intravenous cannula with physiological saline solution after the injection.

Dosage forms and strengths

- Injection contains 1 mmol gadobutrol/mL (equivalent to 604.72 mg gadobutrol/mL) and is available in vials and prefilled syringes

Contraindications

- Hypersensitivity reaction

Precautions

- Nephrogenic Systemic Fibrosis has occurred in patients with impaired elimination of GBCAs.
- Higher than recommended dosing or repeated dosing appears to increase the risk.
- Hypersensitivity: Anaphylactic reactions with cardiovascular, respiratory or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred.
- Monitor patients closely for need of emergency cardio-respiratory support.

Adverse reactions

- Headache, nausea, injection site reaction and feeling hot.
- Nephrogenic systemic fibrosis
- Hypersensitivity reactions
- Cardiac arrest

Pregnancy category : C

Conference Attended / Poster Presentation

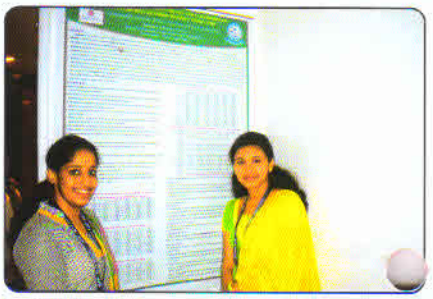
Dr. S. Ananda Thangadurai, Mr. S. Anandkumar and III.Pharm.D students participated in Pharmacy Practice Module Advanced learning series - 7 at Vinayaga Missions College of Pharmacy, Salem on 2nd, 3rd & 4th July 2015.

Dr. T. Suthanth, Ms. D. Saranya Shanmugapriya, M.Pharm and IV.Pharm.D students participated in "National conference on pharmacoeconomics, pharmacovigilance, pharmaceutical care and clinical research outcomes" at PSG College of Pharmacy, Coimbatore on 27th and 28th of June 2015. Our students and faculty presented their poster during the scientific session of the conference.

Paper Publication

Dr. A. Palanisamy published an original research article on "Sensitivity of Montreal Cognitive Assessment in Comparison with Mini Mental Status Examination in Testing Cognitive Status in Epilepsy Patients with Phenytoin Monotherapy" in American Journal of Phytomedicine and Clinical Therapeutics 2015;3(3):237-44. (Impact factor - 3.2)

ACTIVITY		NUMBERS
Drug information queries answered	-	52
No. of Patients counseled	-	1055
No. of ADRs Reported	-	5



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Please send your suggestions to

The Chief Editor

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