CHIPS REGIMEN

Drug Information News Letter
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HVTN 702

The first HIV vaccine efficacy study to launch anywhere in seven years is now testing whether an experimental vaccine regimen safely prevents HIV infection among South African adults. The study, called HVTN 702, involves a new version of the only HIV vaccine candidate ever shown to provide some protection against the virus. HVTN 702 aims to enroll 5,400 men and women, making it the largest and most advanced HIV vaccine clinical trial to take place in South Africa, where more than 1,000 people become infected with HIV every day.

HVTN 702 begins just months after interim results were reported for HVTN 100, its predecessor clinical trial, which found that the new vaccine regimen was safe for the 252 study participants and induced comparable immune responses to those reported in RV144.

The experimental vaccine regimen being tested in HVTN 702 is based on the one investigated in the RV144 clinical trial in Thailand led by the U.S. Military HIV Research Program and the Thai Ministry of Health. The Thai trial delivered landmark results in 2009 when it found for the first time that a vaccine could prevent HIV infection, albeit modestly. The new regimen aims to provide greater and more sustained protection than the RV144 regimen and has been adapted to the HIV subtype that predominates in southern Africa, a region that includes the country of South Africa.

The experimental vaccine regimen tested in the Thai trial was found to be 31.2 percent effective at preventing HIV infection over the 3.5-year follow-up after vaccination. In the HVTN 702 study, the design, schedule and components of the RV144 vaccine regimen have been modified in an attempt to increase the magnitude and duration of vaccine-elicited protective immune responses.

HVTN 702 Phase 3 Trail in Soth Africa

- HIV negative volunteers enrolled and tested for HIV infection 3-months for a maximum of 36 months

Study Arm	Number Ppts	Months 0	Month 1	Month 3	Months 6	Month 12
Vaccine	2700	ALVAC-HIV (vCP2438)	ALVAC-HIV (vCP2438)	ALVAC-HIV+ Bivalent Subtype C gp 120/MF59^R	ALVAC-HIV+ Bivalent Subtype C gp 120/MF59^R	ALVAC-HIV+ Bivalent Subtype C gp 120/MF59^R
Placebo	2700	Placebo	Placebo	Placebo+ Placebo	Placebo+ Placebo	Placebo+ Placebo
Total	5400					

- Sample size selected to achieve 90% power to reject HO : VE < 25% if VE = 50% [VE over 24 months of follow-up]

Reference : www.nih.gov/news-events/news-releases/first-new-hiv-vaccine-efficacy-study-seven-years-has-begun

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TODAY'S MUST WATCH

The following are few important drugs approved by US FDA during the month October-December 2016.

BRAND	DRUG	INDICATION
Eucrisa	Crisaborole	Atopic dermatitis
Soliqua 100/33	Insulin glargine and Lixisenatide	Inadequately controlled type II diabetes
Xultophy 100/3.6	Insulin degludec and Liraglutide	Inadequately controlled type II diabetes
Zinplava	Bezlotoxumab	Recurrent Clostridium difficile infection in patients receiving antibacterial treatment
Spinraza	Nusinersen	Spinal muscular atrophy
Vemlidy	Tenofovir alafenamide	Chronic hepatitis B

- **Soliqua 100/33:** Is a combination of insulin glargine, a basal insulin analog, and lixisenatide, a GLP-1 receptor agonist. It is specifically indicated as an adjunct to diet and exercise to improve glycemic control in adults with type II diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide. It is generally preferred in patients with inadequate glycemic control, on less than 30 units of basal insulin or on lixisenatide. Its starting dosage is 15 units (15 units insulin glargine/5 mcg lixisenatide) given subcutaneously once daily.

  Reference : www.centerwatch.com/drug-information/fda-approved-drugs

- **Nusinersen:** Is the first drug approved by US FDA to treat children and adults with spinal muscular atrophy (SMA), a rare and often fatal genetic disease. It is administered via injection into cerebrospinal fluid, is an antisense oligonucleotide aimed at increasing concentrations of survival motor neuron (SMN) protein, which is underexpressed in SMA.

  Reference: www.medscape.com/viewarticle/873718

STUDENTS CORNER

Link between statin use and risk of Parkinson's Disease!!!

A recent study carried out on 20,000 Parkinson's disease (PD) patients to evaluate the association between use of statins and high or low risk of PD showed that use of statin is associated with increased risk of PD. This finding is contrast to previous research suggesting the statins have a protective effect for PD. While high cholesterol has been shown to have a protective effect on the risk for PD, the role of statin use now has been the subject of debate.

In the recent cross-sectional analysis, the use of cholesterol- lowering drugs, including statins or nonstatins, was associated with a significantly higher prevalence of Parkinson's disease (odds ratio [OR], 1.61 - 1.67; $P < .0001$) after adjustment for age, sex, and other comorbidities, such as hyperlipidemia, diabetes, hypertension, and coronary artery disease. The associations of cholesterol-lowering medications with PD were strongest among patients with hyperlipidemia, and there were no significant differences between lipophilic or hydrophilic statins, as well as the other nonstatin cholesterol-lowering drugs, in their effect on PD risk. Scientists suggest the possibility of statins blocking not only the cholesterol synthesis but also synthesis of coenzyme Q10 that is essential for cell function as the mechanism increased risk of PD. In the cross-sectional analysis, both statins and nonstatin cholesterol-lowering drugs were associated with PD, but in the lagged case-control analysis of treatment duration, only statins remained significantly associated with PD risk.

Reference : Nancy A. Melville. Statin Use Linked to Increased Parkinson's Risk. American Neurological Association (ANA) 2016 Annual Meeting.

CLINICAL CONNECTION

Drug safety communication: Pioglitazone

- As a result of an updated review, the U.S. Food and Drug Administration (FDA) has concluded that use of the type 2 diabetes medicine pioglitazone may be linked to an increased risk of bladder cancer. The labels of pioglitazone-containing medicines already contain warnings about this risk, and we have now approved label updates to describe the additional studies we reviewed.
- Health care professionals should not use pioglitazone in patients with active bladder cancer, and should carefully consider the benefits and risks before using pioglitazone in patients with a history of bladder cancer.
- Patients should contact their health care professionals if they experience any of the following signs or symptoms after starting pioglitazone, as these may be due to bladder cancer:

✔ Blood or a red color in the urine
✔ New or worsening urge to urinate
✔ Pain when urinating

Reference : www.fda.gov/Drugs/DrugSafety/ ucm519616.htm

NSAIDs and Heart Failure.

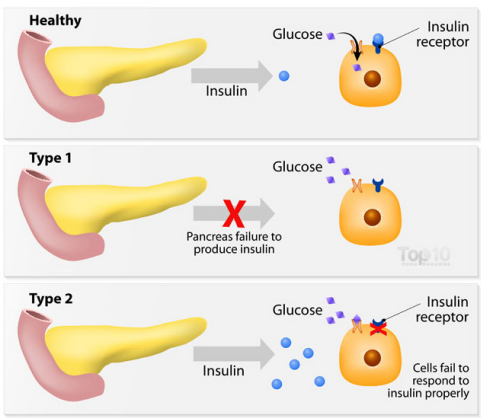
- A nested case control study was done to investigate the cardiovascular safety of non-steroidal anti-inflammatory drugs (NSAIDs) and estimate the risk of hospital admission for heart failure with use of individual NSAIDs. Participants were enrolled from five population based healthcare databases from four European countries (the Netherlands, Italy, Germany, and the United Kingdom).
- The study results suggest that the use of any NSAID (use in preceding 14 days) was found to be associated with a 19% increase of risk of hospital admission for heart failure (adjusted odds ratio 1.19; 95% confidence interval 1.17 to 1.22), compared with past use of any NSAIDs (use >183 days in the past). Risk of admission for heart failure increased for seven traditional NSAIDs (diclofenac, ibuprofen, indomethacin, ketorolac, naproxen, nimesulide, and piroxicam) and two COX 2 inhibitors (etoricoxib and rofecoxib). Odds ratios ranged from 1.16 (95% confidence interval 1.07 to 1.27) for naproxen to 1.83 (1.66 to 2.02) for ketorolac. Risk of heart failure doubled for diclofenac, etoricoxib, indomethacin, piroxicam, and rofecoxib used at very high doses (≥2 defined daily dose equivalents), although some confidence intervals were wide. Even medium doses (0.9-1.2 defined daily dose equivalents) of indomethacin and etoricoxib were associated with increase risk. There was no evidence that celecoxib increased the risk of admission for heart failure at commonly used doses.
- This study concluded that the risk of hospital admission for heart failure associated with current use of NSAIDs appears to vary between individual NSAIDs, and this effect is dose dependent.

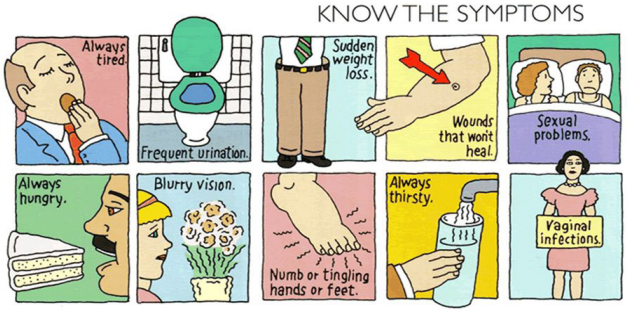
Reference: Arfè A, Scotti L, Varas-Lorenzo C, Nicotra F, Zambon A, Kollhorst B, et al. Non-steroidal anti-inflammatory drugs and risk of heart failure in four European countries: nested case- control study. BMJ 2016;354:i4857

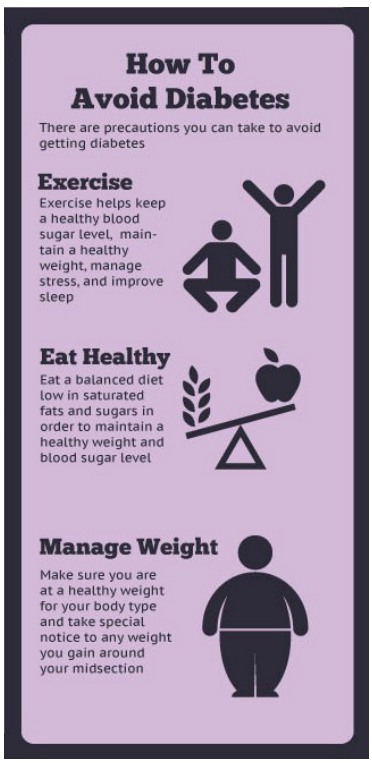
ADVICE

14th NOVEMBER : WORLD DIABETES DAY

✔ Diabetes is a disease in which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood
✔ Diabetes is due to either the pancreas not producing enough insulin or the cells of the body not responding properly to the insulin produced.
✔ Globally, an estimated around 480 million adults were living with diabetes, causing 1.5 million deaths annually.
✔ Asia accounts for 60% of the world's diabetic population.







STAFF PUBLICATIONS

A total of 15 publications were published by our staff members during the month October to December 2016. A few of them are listed below.

1. B. Praveen Kumar, S. Vidyadhara, T.E.G.K. Murthy, B. Venkateswara Rao and V. Nikhila. A Novel Reverse Phase Liquid Chromatographic Method Development And Validation For The Simultaneous Estimation Of Atorvastatin, Ezetimibe And Fenofibrate In Bulk And Tablet Dosage Form. International Journal of Pharmaceutical Sciences and Research, 2016; Vol. 7(10): 4145-4151.
2. B. Praveen Kumar, S. Vidyadhara, T. E. G. K. Murthy, J. Ramesh Babu and R. L. C. Sasidhar. Development and validation of novel UV spectrophotometric and RP-HPLC method for the estimation of paroxetine hydrochloride in bulk and pharmaceutical dosage forms. Der Pharmacia Lettre, 2016, 8 (11):1-9.
3. B. Venketeswara Rao, S. Vidyadhara, RLC Sasidhar, T.N.V.Ganesh Kumar & Md.Rokiya. A Novel Stability Indicating RP-HPLC Method Development and Validation for The Simultaneous Estimation of Losartan Potassium, Ramipril and Hydrochlorothiazide in Bulk and Pharmaceutical Dosage form. Eurasian Journal of Analytical Chemistry, 2016, 11(5), 255-265.
4. B. Sudheer, S. Vidyadhara, M. V. Basaveswara Rao, RLC. Sasidhar and K. Venkata Ramana. Formulation And Characterization Of Diltiazem Hcl Matrix Tablets By Employing Electrolytes With Gum Kondagogu. International Journal of Pharmaceutical Sciences and Research, 2016; Vol. 7(11): 4592-4601.
5. S. Vikas, S. Vidyadhara, D. Sandeep and M. Hyndavi. A Case Report on Scrub Typhus Fever. The Indian Pharmacist, Vol.XIV, No 5, November 2015.
6. T. Balakrishna, S. Vidyadhara, T. E. G. K. Murthy, K. Viswanadh, M. Tejasri. Formulation and Evaluation of Orodispersible Tablets of Zolmitriptan. Asian Journal of Pharmaceutics, Oct-Dec 2016 (Suppl), 10 (4), S683.
7. J. Ramesh Babu, S. Vidyadhara, B. Sowjanya Lakshmi. Design and in vitro Evaluation of Gastroretentive Drug Delivery System of Cefixime Trihydrate. Asian Journal of Pharmaceutics, Oct-Dec 2016, (Suppl), 10 (4), S595.
8. P.Vijetha. J.Ramesh Babu, S.Vidyadhara. Phytochemical And Pharmacological Evaluation Of Commiphora Mukul For Antidepressant Activity In Albino Mice. Asian Journal of Pharmaceutical and Clinical Research, Vol 10, Issue 1, 2017, 1-4.
9. S. Vidyadhara, R. L. C. Sasidhar, S.Sivaprasad, S.Vikas and DL.Harika. Dissolution rate enhancement of irbesartan and development of fast-dissolving tablets. Egyptian Pharmaceutical Journal. 2016, 15:150–157.

Personality Development Workshop by Dr. Jagannadha Rao, at CHIPS (03-05/10/2016)

IPA Devinder Pal National Elocution Competition-2016 organized by CHIPS (25/10/2016)

CHIPS PHARMA EXPO - 2K16 Organized by CHIPS (17-19/11/2016)

ANU Inter Collegiate (Men & Women) Table Tennis Tournament Organized by CHIPS (08/12/2016)

An Inter College Sports & Co-Curricular Event CHIPSOIREE-2K16 Organized by CHIPS (09-10/12/2016)

We are Glad to Receive your Feedback to chipsregimen@gmail.com

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