Medical News

Published (Web): July 23, 2014

Home diagnostic kit for type 1 diabetes

Published Date: July 16, 2014

A team of researchers have designed a nanochip-based, cheap, hand-held diagnostic kit to diagnose type-1 diabetes at home. The kit is particularly useful to individuals who are at-risk of type-1 diabetes.

According to Dr. Brian Feldman, Assistant Professor, Stanford University School of Medicine, the novel diagnostic kit is able to predict diabetes onset effectively; the at-risk individuals are able to understand diabetes better.

The kit is devised to differentiate type-1 and type-2 diabetes by fluorescence-based detection of autoantibodies. Clinical trials were conducted to assess the efficacy, and results of diabetic and non-diabetics were compared. The nano-particles based microchip differentially diagnosed type-1 diabetic cases, within minutes. When compared to conventional assays, the microchip-based assay utilizes smaller volume of blood sample.

Extra dose of OPV to boost immunity

Published Date: July 14, 2014

A recent study published in *The Lancet* suggest that administration of an extra dose of oral polio vaccine (OPV) in children less than 5 years of age might boost prophylaxis against polio infection. The supplemental dose is particularly useful for children living in polio-endemic countries. The study was conducted by researchers at Christian Medical College, Vellore, India.

According to Dr. Jacob John, study guide, supplementary OPV dose to already-vaccinated children might improve immunity against polio infections in endemic regions. Additional prophylaxis may also prevent international spread and associated polio outbreaks.

The present study suggested that additional OPV dose significantly boosted circulatory antibody levels against polio antigens and intestinal immunity against pathogen. However, the additional benefits were not evident in non-supplemented children.

Letrozole is effective against PCOD

Published Date: July 11, 2014

Women diagnosed with polycystic ovarian syndrome (PCOD) might be effectively treated by Letrozole, a breast cancer drug, according to a study published in the *New England Journal of Medicine*. PCOD negatively affect ovulation and fertility rate in women, and clomiphene citrate is being prescribed for treatment.

According to Dr. Richard Legro, Professor of Obstetrics and Gynecology, Penn State University, Letrozole could be a simple, cheaper, effective and comparatively safer option for PCOD treatment.

Clomiphene acts by stimulating ovulation and increase risk of multiple births. However, Letrozole blocks estrogen biosynthesis, and stimulate the ovaries.

The present study involved 750 women with PCOD. The subjects were randomly assigned to receive either Letrozole or Clomiphene. The treatment was continued over five menstrual cycles with periodical dosage increase for each cycle. About 28% conception rate was observed in Letrozole treated women, compared with 19% in Clomiphene group.

The twin pregnancy rate in Letrozole and Clomiphene treated women was 3% and 7% and ovulation rate was 62% and 48%, respectively

Clomiphene might cause hot flashes, while Letrozole treatment is associated with dizziness and fatigue. The incidence of birth defects is same and rare for both drugs.

Inhalation powder insulin approved by USFDA

Published Date: July 03, 2014

The United States Food and Drug Administration (USFDA) has approved Afrezza, a fast-acting inhalation powder insulin for management of type-2 diabetes and to improve glycemic control. Afrezza should not be used as an alternative to other long-acting insulin. In type-1 diabetics, Afrezza is indicated as a combined therapy with other long-acting insulin formulations. Afrezza should be administered at the beginning or within 20 minutes after a meal.

Afrezza is contraindicated in diabetics with smoking habits. It should not be used to treat diabetic ketoacidosis.

The safety and efficacy of Afrezza was evaluated in 3, 017 subjects including 1, 026 type-1 diabetics and 1, 991 type-2 diabetics. The study duration was 24 weeks. In type-1 diabetics, the efficacy of mealtime Afrezza was compared with mealtime insulin aspart and both treatments in addition with basal insulin.

Clinically significant blood sugar control and reduction in HbA1c was observed in patients treated with Afrezza and basal insulin. When compared to insulin aspart, Afrezza notably reduced HbA1c levels in treated patients. The results were statistically significant.

In type-2 diabetics, Afrezza was evaluated in addition with oral anti-diabetic drugs. When compared to placebo, the efficacy of mealtime Afrezza plus oral antidiabetic drugs was remarkable, in terms of HbA1c reduction.

Reference: DrugsUpdate.com

New Approval

Kerydin approved for toenails onychomycosis treatment

Published Date: July 14, 2014

The United States Food and Drug Administration (USFDA) has approved Kerydin (5% Tavaborole topical solution) for treatment of onychomycosis of toenails due to mycotic infections such as *Trichophyton mentagrophytes* or *Trichophyton rubrum*. Kerydin should be applied onto the affected area once daily for 48 weeks. Due to low systemic absorption, no systemic adverse events were reported.

Two multi-centric, randomized, double-blinded clinical trials were conducted to assess the safety and efficacy of anti-fungal drug. About 1194 subjects who were aged between 18 and 88 years were included in the study. The participants were treated for 48 weeks, and assessed at 52nd week. The primary end point of the study was complete cure with no evident fungal infection. The secondary endpoint was complete or almost complete cure with less than 10% remnant infections.

At week 52, primary endpoint was achieved by 6.5% and 9.1% of treated subjects in first and second study. Similarly, secondary endpoint was evident in 31.1% and 35.9% of treated patients in first and second study, respectively. Some of the commonly reported adverse events of Kerydin were ingrown toenail, application site reactions including dermatitis, exfoliation and erythema.

USFDA approved Beleodaq

Published Date: July 07, 2014

The United States Food and Drug Administration (USFDA) has approved Beleodaq (Belinostat) for management of peripheral T-cell lymphoma (PTCL). Beleodaq was approved with orphan drug status based on the agency's accelerated approval process.

Beleodaq inhibit certain enzymes that play vital role in T-cell malignancy. Beleodaq is indicated primarily for PTCL patients with either refractory or relapse forms.

Clinical trials involving 129 PTCL patients with refractory or relapse history were conducted to assess the safety and efficacy of Beleodaq. The subjects received Beleodaq treatment until disease progression or development of drug intolerance. Among the participants, complete or partial response was observed in 25.8% patients.

Some of the common, non-serious adverse events of Beleodaq are anemia, nausea or vomiting, fever and general weakness.

USFDA approved Sivextro for ABSSSI treatment

Published Date: June 30, 2014

The United States Food and Drug Administration (USFDA) has approved Sivextro (Tedizolid phosphate) for treatment of adult acute bacterial skin and skin structure infections (ABSSSI). A month ago, the agency approved Dalvance (Dalbavancin) for treatment of ABSSSI. Sivextro belongs to oxazolidinone class of drugs. Sivextro is to be marketed as oral and intravenous formulations. Sivextro is a once-daily drug that can be taken before or after meals.

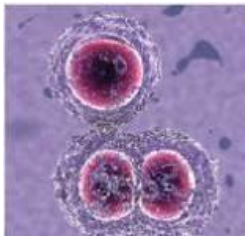
The recommended dosage of Sivextro is 200 mg, once daily for six days. Some of the common adverse events of Sivextro are dizziness, diarrhea, vomiting and headache.

The approval of Sivextro was based on two international, phase-III clinical trials. The efficacy of 200 mg dose, OD for six days was statistically equivalent to 600 mg of Linezolid, t.i.d. for 10 days.

Efinaconazole approved for onychomycosis treatment

Published Date: June 23, 2014

The United States Food and Drug Administration (USFDA) has approved Efinaconazole (Jublia) (10%) topical formulation for treatment of toenail onychomycosis. The drug is to be manufactured by Valeant Pharmaceuticals. Efinaconazole solution should be applied daily by using in-built brush applicator.



The first triazole class drug is primarily indicated for treatment of distal lateral subungual onychomycosis. Previously, the agency declined to approve Jublia due to queries related to drug chemistry and manufacturing practices.

Two randomized, placebo-controlled, double-blinded, phase-3 clinical trials involving 1, 655 onychomycosis patients were conducted to assess the safety and efficacy. Complete cure was reported in 17.8% and 15.2% of subjects, in study 1 & 2, respectively. However, cure rate was 3.3% and 5.5% in the placebo group. Complete cure is defined as negative fungal culture and potassium hydroxide test at week 52.

Some of the reported common adverse events include application site vesicles and dermatitis. No reports of drug interactions and acute hepatic damage.

Reference: DrugsUpdate.com

Recent Health Issues

Caffeine may boost long-term memory

January 13, 2014

Numerous studies have suggested that caffeine has many health benefits. Now, new research suggests that a dose of caffeine after a learning session may help to boost long-term memory. This is according to a study published in the journal *Nature Neuroscience*.

The research team, led by Daniel Borota of the Johns Hopkins University in Baltimore, notes that although previous research has analyzed the effects of caffeine as a cognitive enhancer, whether caffeine can impact long-term memory has not been studied in detail.

To find out, the investigators analyzed 160 participants aged between 18 and 30 years.

On the first day of the study, the participants were shown pictures of different objects and were asked to identify them as "indoor" or "outdoor" items.

Soon after this task, they were randomized to receive either 200 mg of caffeine in the form of a pill, or a placebo tablet.

The next day, the participants were shown the same pictures as well as some new ones. The researchers asked them to identify whether the pictures were "new," "old" or "similar to the original pictures."

From this, the researchers found that subjects who took the caffeine were better at identifying pictures that were similar, compared with participants who took the placebo.

However, the researchers note that both groups were able to accurately distinguish whether pictures were old or new.

The team conducted further experiments using 100 mg and 300 mg doses of caffeine. They found that performance was better after the 200 mg dose, compared with the 100 mg dose, but there was no improvement after the 300 mg of caffeine, compared with 200 mg.

"Thus, we conclude that a dose of at least 200 mg is required to observe the enhancing effect of caffeine on consolidation of memory," the study authors write.

Too much protein in middle age 'as bad as smoking'

March 05, 2014

Two new studies conclude that low protein intake may hold the key to a long and healthy life, at least until old age. They also emphasize the need to examine not only calories when deciding what constitutes a healthy diet, but also where those calories come from - such as whether protein is animal or plant-based.

Another key finding is the suggestion that while a high-protein diet may in the short term help people lose weight and body fat, in the long term it may harm health and reduce lifespan.

Both studies are published in the journal *Cell Metabolism*.

The first study was led by Valter Longo, a professor at the University of Southern California, who counts longevity and cell biology among his areas of expertise.

He and his colleagues showed that high protein consumption is linked to increased risk of cancer, diabetes and death in middle-aged adults, although this was not the case for older adults who may benefit from moderate protein consumption. Also, the effect is much reduced when the protein comes from plant sources.

The second study was led by Stephen Simpson, a professor at the University of Sydney in Australia, whose group works at the interface of physiology, ecology, and behavior. From studying mice, he and his fellow authors concluded that diets low in protein and high in carbohydrates are linked to the longest life spans.

Both studies suggest it is not just calories, but also diet composition - particularly in terms of amount and type of protein - that may determine the length and health of a lifespan.

Prof. Longo says: "We studied simple organisms, mice and humans, and provide convincing evidence that a high- protein diet - particularly if the proteins are derived from animals - is nearly as bad as smoking for your health."

Simulated human heart used to test drugs' effects

July 21, 2014

Heart-related side effects of drugs are often only exposed once the drug is used on patients in clinical trials, at which point it is too late. But a scientist in the UK has spent 10 years developing a breakthrough new way to safely test a drug's cardiovascular effects without having to use human or animal trials - by using samples of beating heart tissue.

Dr. Helen Maddock, from the Centre for Applied Biological and Exercise Sciences at Coventry University, is an expert in cardiovascular physiology and pharmacology. She believes her new technique could improve the quality of treatment and save hundreds of patients' lives.

The new technique allows scientists to assess adverse cardiovascular effects of new drugs first without using animal or human trials.

It works by using an in vitro technique - meaning "in glass," as it is carried out in a lab environment rather than in a living organism. Dr. Maddock uses a sample of heart tissue attached to a rig that enables the muscle to lengthen and shorten while being stimulated by an electrical impulse.

This action imitates the biomechanical performance of cardiac muscle, she explains.

Next, scientists can add trial drugs to the tissue in order to conclude whether or not they have a negative effect on the contraction of the muscles in the heart. Previously, researchers could only perform such a test on living animals, often with inconclusive results.

Because a major reason for why many medical treatments fail is negative effects of the drugs on the cardiovascular system, Dr. Maddock's technique could revolutionize the way drugs are tested before they even reach animal or human trials.

Her technique, called a "simulated" cardiovascular system and also known as a work-loop assay, is the most realistic heart muscle dynamic model in the world at present, one that creates the possibility of determining the negative effects of certain drugs early and without great cost.

In addition to saving lives, it could expedite development of drug treatments that work without major cardiovascular side effects.

"I'm delighted that our research is at a stage where we can confidently say the work-loop assay we've created is the world's only clinically relevant in vitro human model of cardiac contractility," says Dr. Maddock. "It has the potential to shave years off the development of successful drugs for a range of treatments."

To implement her technique in the pharma industry, she formed a spin-out company from Coventry University called InoCardia Ltd, which has already received a £250,000 ($427,000) investment from Mercia Fund Management, a UK-based technology firm.

Dr. Maddock adds: "Both the pharma industry and regulators recognize that existing methods of assessing the contractility of the heart are fraught with problems, so we're incredibly excited to be able to introduce a new way to accurately determine the safety of drugs in respect of the heart without the need to test on humans or animals."

She and her company are currently in discussions with a multinational biopharmaceutical company regarding applying her assay in industry.

Scientists discover new way to make human platelets

July 21, 2014

(HealthDay News) -- Scientists report they have discovered a new way to make fully functional human platelets, which are the blood cells that form clots.

Using human stem cells and a device called a bioreactor, which mimics the body's natural way of producing blood cells but on a larger scale, the researchers said their method eliminates risks and complications associated with donor blood transfusion. Those include a five-day shelf-life, contamination, rejection and infection. They added that their findings could help meet increasing global demand for donor blood.

"The ability to generate an alternative source of functional human platelets with virtually no disease transmission represents a paradigm shift in how we collect platelets that may allow us to meet the growing need for

blood transfusions," study author Jonathan Thon, from the division of hematology at Brigham and Women's Hospital in Boston, said in a hospital news release.

Blood cells, such as platelets, are made in bone marrow. The bioreactor, the researchers explained, combines the major components of bone marrow and models its composition and blood flow characteristics.

"By being able to develop a device that successfully models bone marrow represents a crucial bridge connecting our understanding of the physiological triggers of platelet formation," study senior author Joseph Italiano Jr., of the division of hematology at Brigham and Women's Hospital and the Vascular Biology Program at Boston Children's Hospital, said in the news release.

The researchers hope to begin human clinical trials in 2017.

"The regulatory bar is appropriately set high for blood products and it is important to us that we show platelet quality, function and safety over these next three years since we'll likely be recipients of these platelets ourselves at some point," Thon said.

One expert agreed the findings could change the way platelets are collected.

"A major factor that has limited our ability to compare bioreactor platelets to donor platelets is the inefficiency of growing platelets, a problem that slows progress of clinical research," Dr. William Savage, medical director of the Kraft Family Blood Donor Center at Dana Farber Cancer Institute/Brigham and Women's Hospital, said in the news release. He was not part of the study. "This study addresses that gap, while contributing to our understanding of platelet biology at the same time."

In the United States, more than 2.17 million platelet units from donors are transfused each year to treat trauma patients and those undergoing chemotherapy, organ transplants and surgery, the researchers noted.

The study, published July 21 in the journal *Blood*, was partially funded by the U.S. National Institutes of Health. Thon and Italiano are co-founders of Platelet BioGenesis, a company that aims to produce donor-independent human platelets from human stem cells.

Source: http://www.medicalnewstoday.com/popular; accessed on July 22, 2014.

'Exciting' drug flushes out HIV

July 22, 2014

Scientists say they have made an "exciting" step towards curing HIV by forcing the virus out of hiding. HIV can become part of someone's DNA and lie dormant for decades, making a cure impossible. Early stage research in six people, reported at the Aids 2014 conference, shows that low-dose chemotherapy can awaken the virus.

Experts said it was a promising start, but it was unlikely the drug would work on its own to cure HIV. Anti-viral drugs can drive HIV down to undetectable levels in the bloodstream, meaning people who are HIV-positive can have a near-normal life expectancy. But there is problem. HIV can incorporate its DNA into our own, where it lies beyond the reach of drugs and the immune system - it is known as the HIV reservoir. When drug treatment stops, the virus can leap out of the reservoir and renew its assault.

A team at Aarhaus University in Demark tried using a chemotherapy drug, romidepsin, which is used in lymphoma. Six HIV patients with undetectable levels of the virus were enrolled into trial. They each received a reduced dose of romidepsin once a week for three weeks. There was a noticeable jump in viral levels in the blood in five of the patients.

One of the scientists involved, Dr Ole Sogaard, told the BBC: "Every step forward is always exciting, and I think this is quite important." He said there had been a lot of skepticism about the drug being potent enough. "We've shown it is possible to kick the virus out of the cells, the next step is to actually kill the cells.

"The trial now moves into a new phase which combines the romidepsin with something to enhance the immune system and in our case this is an HIV vaccine." Side-effects were those normally associated with chemotherapy, including fatigue.

There are still many challenges ahead. The team cannot say what proportions of cells hiding HIV are being activated by romidepsin. Another looming question is which reservoirs are being successfully targeted. HIV can hide in immune cells in the blood, but there are bigger reservoirs in the gut and central nervous systems and it is

not clear whether they are activated by the blood-based chemotherapy.

"We know it's a step forwards, but we don't know how big, it might just be a single step or it could be a great leap forward," Dr Sogaard added.

Romidepsin works by "relaxing" tight coiled up bundles of DNA. This exposes the hidden HIV genetic code and leads to the production of new viruses.

Dr Andrew Freedman, a reader in infectious diseases at Cardiff University, told the BBC: "As a proof of concept it does look promising. "The search for a cure is very much on, it's not going to be easy and it's unlikely a single drug like this would be sufficient. "There's a lot of doubt it would be enough to deplete the reservoir completely.

"Most people think a single approach will not be enough, a drug like this perhaps needs to be combined with vaccines or even gene-therapy.

Source: http://www.bbc.com/news/health-28159515, accessed on July 22, 2014.

NICE recommendation means more people take atorvastatin to prevent heart disease

The Pharmaceutical Journal, 22 JUL 2014

New NICE guidelines recommend an extra 4.5 million people in England take statins to prevent cardiovascular disease

Atorvastatin is set to become the most prescribed drug in the UK following changes to cardiovascular disease (CVD) prevention guidelines from the National Institute of Health and Care Excellence (NICE).

The guidelines recommend that all patients with a 10% or greater risk of developing CVD over the next 10 years should be offered atorvastatin 20mg for primary prevention. This cuts the threshold by half, making an extra 4.5 million patients in England eligible for statins.

GPs will use a cardiovascular risk assessment tool known as QRISK2 to assess the risk of patients.

Some 7 million people in the UK are taking a statin, costing the NHS £150 million each year. Based on 80% patient compliance, NICE estimates that the increased use of statins, offset by the reduction in costs associated with cardiovascular events, would cost the NHS an additional £52million each year.

Atorvastatin is already seeing growth in volume terms. In 2013, it accounted for 18.2m prescription items dispensed in England, while competing product, simvastatin, sat at 39.9m items - being the most dispensed drug in England. However, atorvastatin's volumes have risen by 6m items compared with 2012 following the expiry of its patent, while simvastatin items fell by 3m from the 42.6m million peak in 2012.

The guidelines also recommend that patients being treated for CVD should be offered the higher dose of 80mg atorvastatin. Patients who are stable on a low- or middle-intensity statin (see 'Reduction in low-density lipoprotein cholesterol') should discuss the benefits of switching to a high-intensity statin when they have a medication review, it adds.

Although the guidelines increase the number of patients eligible for statins, it does not mean all patients should receive them, stressed Mark Baker, director of the centre for clinical practice at NICE. "The guidance recognizes the importance of choice in preventing CVD, and that this should be guided by information on the trade-off between risks and benefits."

However, the "weight of evidence clearly shows statins are safe, and clinically and cost-effective," Baker added.

The new guidance could mean better discussions with patients, said Helen Williams, consultant pharmacist for cardiovascular disease for south London. "The guidance says to offer a statin -which implies a conversation. And that means the patient should be empowered."

The guidance also recommends that all patients with CVD or at high-risk of CVD should eat a diet in which fat intake is 30% or less of total energy intake, and perform at least 150 minutes of moderate-intensity exercise or 75 minutes of vigorous aerobic activity each week.

In 2010 around 180,000 patients died of CVD in England and Wales, and the condition cost the NHS in England around £7.9 billion.

Hypertension and beta-blockers may raise risk of psoriasis

The Pharmaceutical Journal, 16 JUL 2014

US researchers show association among hypertension, antihypertensive medications and psoriasis. Fndings provide novel insights into the association among hypertension, antihypertensive medications and psoriasis

Longstanding hypertension and long-term use of beta-blocker drugs may each be risk factors for developing psoriasis, analysis suggests. The research, based on a large US dataset which appears in *JAMA Dermatology*, shows that women who had been hypertensive for six or more years and those who regularly used beta-blockers had a significantly increased likelihood of developing the skin condition.

Beta-blockers are among several classes of medication that exacerbate psoriasis, along with lithium, antimalarials and interferons, according to the author of a related commentary.

"These findings provide novel insights into the association among hypertension, antihypertensive medications and psoriasis," write Shaowei Wu, from Brown University in Providence, Rhode Island, United States, and co-authors. "However, further work is necessary to confirm our findings and clarify the biological mechanisms that underlie these associations."

Among 77,728 US women who participated in the Nurses' Health Study, 843 developed psoriasis. Compared with those who did not suffer hypertension, women who had been hypertensive for six or more years had a 1.27-fold increased risk of developing psoriasis. The risk was lower in women who were currently taking antihypertensive medication than in those who were not (adjusted hazard ratios [HR] 1.31 vs 1.49).

Among individual antihypertensive drugs, a marginal association was found between regular use of beta-blockers and risk of psoriasis (multivariate-adjusted HR 1.18); this association was dose-dependent, with the risk being highest among those who had used beta-blockers regularly for six or more years (HR 1.39). No other individual antihypertensive drug was associated with psoriasis risk.