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**PHARMA
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EXPERT DESK



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INDIAN DEVICE FOR CANCER TREATMENT GIVEN 'BREAKTHROUGH' TAG BY USFDA BRANCH

Earlier this month, the 'Cytotron,' a medical invention by Dr Rajah Vijay Kumar, a Bengaluru based scientist, received a 'breakthrough device' tag in cancer care by the Centre for Devices and Radiological Health, a branch of the United States Food and Drug Administration (USFDA) responsible for the pre-market approval of all medical devices.

The machine, "intended to stop the cancer tissue from multiplying, growing and spreading," is claimed to be the outcome of 32 research.

The Cytotron works on the tissue engineering principles of human cells, altering how certain proteins are regulated to prevent them from multiplying and spreading in case of cancer or promote the growth of cells where required.

The inventors claim to have moved away from 'destroying, killing or obliterating cancer tissues' to a method of communicating with the cellular command and control, and stop it from growing and spreading to other parts of the body. Cancer cells are cells that have just gone out of control. By appropriately addressing the right methodology and specific protein pathways, you can drive the cancer cells into old age, push them into accelerated ageing, and finally, apoptosis (programmed cell death). Once this stage is achieved, your body's immune system takes over time and the cancer cells are recycled. This is the philosophy of Cytotron.

What does Cytotron do in Cancer Cells?

Any cell in our body can multiply anywhere upto 50 times before becoming senescent, which means it can no longer further that process. After the 50th division, there is a flag planted down, where a protein called p53, a programmed cell death protein, is expressed in old age cells. This ensures the cell doesn't multiply any further. This process is driven by the pro-apoptotic protein p53, which regulates apoptosis. Unfortunately, in cancer cells, this process doesn't happen because the protein is mutated or is not expressed, as they do not receive the signal to do so.

Naturally, these cells don't know when to stop multiplying and eventually progress to grow as an organ in the body or a life form. As they grow, they land up with a resource crunch. Then, these cells look at forming new colonies and start spreading with their “survival instincts” taking over. Cancer produces a very special kind of cell, called EMT cells or cancer stem cells (CSCs), that spread to another location and then it builds up new colonies. As long as the cancer is growing, the body's immune system does not attack it. On the contrary, it protects the cancer tissue. Cancer cells take advantage of this situation, and conquer different organs of the body, until the body cannot function normally.

“Cytotron stops the cancer tissue from multiplying and spreading to other organs. Once the tumor stops growing or spreading, what we do at Cytotron is plant the flag (protein) down, which determines that the cell is old enough to die. The moment this happens, the cell stops growing and once that happens the first reaction of the immune system is to grab the cell and throw it out. The cancer tissue is recycled, and this device also works to convert or transform the cancer stem cells into cells that don't multiply. These are two things that happen when we treat a cancer patient with Cytotron. Depending on which stage of cancer you're being treated at, it stops the cancer cells from spreading. The earlier you go inside the Cytotron, your cancer gets arrested at that point. Once you stop the tumour from growing and spreading, there are other ways you can manage the disease.”

The Cytotron, generically known as a rotational field quantum magnetic resonance, produces fast radio bursts, which modulate the life systems and communicate with cells in the body. At present, the machine is being made at the CARD campus in Bengaluru. The device is approved for clinical use by the Medical Devices Directive (MDD) of the European Council, the SFDA in the Middle East and the Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) in South America.

Cytotron First, The Rest Later

“In India, the Cytotron will cost anywhere between Rs 2.5 to Rs 3 crore,” although they claim to give treatment to people at their centre. For patients diagnosed with cancer, before any surgery, they should ideally be sent straight into the Cytotron so the tumour can be stopped from growing or spreading. “Patient essentially cut down the risk of cancer spreading by going through the Cytotron. If there is a tumour that is causing pain or discomfort, you could do surgery later on. But before doing it, you must go through the Cytotron. Once cancer activity stops, people feel more energetic, they put on weight, and the effects are generally good after patients undergo Cytotron treatment.”

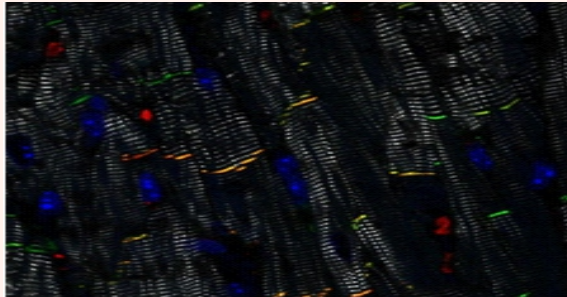
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PROMISING NEW GENE THERAPY APPROACH FOR GENETIC HEART DISEASE

Arrhythmogenic cardiomyopathy (ACM) is a genetic heart disease that affects 1 in 2,000 to 1 in 5,000 people worldwide. It is characterized by arrhythmias and can lead to sudden cardiac arrest. Current treatment of the disease usually consists of antiarrhythmic drugs and implantable cardioverter-defibrillators (ICDs), which are focused solely on treating the symptoms rather than targeting the root of the problem.

Disease of the desmosome



The most frequently affected gene in ACM is PKP2, which encodes the plakophilin-2 protein, an essential part of the desmosomes. Patients with mutations in this gene often have lower levels of the plakophilin-2 protein in their heart muscle cells. The result is that the desmosomes, which are normally built up by meticulously binding all proteins together, now start to fall apart and are broken down by the cell. This weakens the connections between the heart muscle cells, which makes it difficult for them to work together in synchrony, leading to the development of arrhythmias.

This is a microscopic image showing heart muscle cells (gray) in a mouse heart. The plakophilin-2 protein (green) is present in the desmosomes connecting adjacent heart muscle cells. After introduction of the healthy PKP2 gene, extra plakophilin-2 (red) is present in the cells (visible as yellow in places where green and red overlap). This localizes to the desmosomes, leading to their structural recovery.

Gene therapy

With the molecular cause of ACM, the development was based on therapeutic approach that would target this cause and not just the symptoms. By introducing the healthy PKP2 gene into affected heart muscle cells, it might be able to restore plakophilin-2 levels to normal, thereby reinforcing the desmosomes and reducing the occurrence of arrhythmias in these patients.

Improved heart function in the laboratory

It also improved sodium conduction, which is important for heart's ability to contract. Further it was confirmed this improvement of contractility in engineered human heart muscles, which are ring-shaped structures that we can grow in the lab. Heart muscles with a PKP2 mutation contracted better after receiving the healthy PKP2 gene. Finally, to test this strategy in vivo, PKP2 gene replacement was applied in mouse model of ACM. This led to recovery of their desmosomes and heart function.

From lab to clinic

Following the promising laboratory results, the next step is to investigate the clinical potential of this gene therapy approach in ACM patients with PKP2 mutations. Three companies in the United States have announced that they will start clinical trials next year to test the therapeutic effect of this approach in patients. The researchers at the Hubrecht Institute hypothesize that gene replacement therapy would be most useful in the early stages of the disease. Once the disease has progressed so much that parts of the heart muscle have already been replaced by fat tissue, it is uncertain whether this approach would reverse already existing damage. Instead, it is believed that it might be possible to prevent progression of early-stage disease to more severe stages. Although the pre-clinical results and upcoming trials hold great promise, the commercial availability of this approach could still take several years. Apart from the evident need to confirm its efficacy in patients, it is also crucial to address and eliminate any safety concerns before considering its clinical application.

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By

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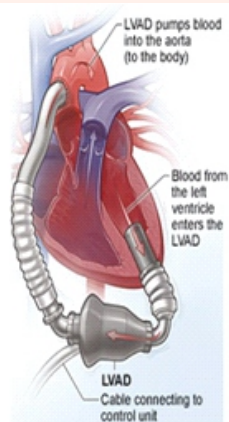
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Novel Study Finds Aspirin-free Regimen Benefits Patients With LVAD

Heart failure (HF) is a frequent cause of inpatient admissions. HF can be categorized based on the left ventricular ejection fraction (LVEF) into systolic and diastolic HF. The former group includes patients with LVEF less than or equal to 40%, also termed heart failure with reduced ejection fraction (HFrEF). Heart failure with preserved ejection fraction (HFpEF) includes those with LVEF greater than or equal to 40%.

Circulatory support with the use of a Left Ventricular Assist Device (LVAD) is an emerging field. Left Ventricular Assist Devices (LVADs) enhance quality and duration of life in advanced heart failure. The burden of nonsurgical bleeding events is a leading morbidity. Aspirin as an antiplatelet agent is mandated along with vitamin K antagonists (VKAs) with continuous-flow LVADs without conclusive evidence of efficacy and safety. The ARIES-HM3 Randomized Clinical Trial assessed the safety and efficacy of excluding aspirin from the antithrombotic regimen in patients with advanced heart failure who have undergone implantation of a fully magnetically levitated left ventricular assist device (LVAD). The clinical trial found that excluding aspirin from the antithrombotic regimen in patients with a levitated left ventricular assist device was safe.

The international clinical trial followed a randomized, double-blind, placebo-controlled design and involved 628 patients across 51 centers in 9 countries. The patients were divided into two groups: one receiving aspirin (100mg/d) and the other receiving a placebo in addition to vitamin K antagonist (VKA) therapy.



The results showed not giving aspirin to patients with advanced heart failure, treated with a fully magnetically levitated LVAD who are receiving VKAs, did not make their survival worse. Furthermore, aspirin avoidance was associated with a significant reduction (34%) in major nonsurgical bleeding events.

In patients with advanced heart failure treated with a fully magnetically levitated LVAD, avoidance of aspirin as part of an antithrombotic regimen, which includes VKA, is not inferior to a regimen containing aspirin, does not increase thromboembolism risk, and is associated with a reduction in bleeding events.

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By

Dr. NEENA ELSA VARGHESE, Pharm. D.,

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STUDENT OUTREACH ACTIVITIES



Department of Pharmacy Practice organised a guest lecture entitled “Promising Innovations and Career Opportunities for Pharma Graduates” by Dr. K. Ranjithkumar, Sr. Project Manager, Leszarians, Chennai for B. Pharm students on 08.10.2024.



Celebrated Ayudha Pooja for all the department and Bus day at RTT ground on 09.10.2024. Performing traditional rituals and festivities to honor and bless our tools and vehicles for prosperity and safety.



IV B. Pharm students observed World Food Day on 17.10.2024 at Thaaai Madi Trust, Sankagiri. Our students donated food and toiletries to the old people at that trust.



Institution Innovation Council organised guest lecture entitled “Stress Management” by Dr. G. Murugananthan, Principal, Swamy Vivekanandha College of Pharmacy, Tiruchengode on 23.10.2024.



Inaugural ceremony for D. Pharm freshers at Srinivasa Mahal on 04.11.2024.



Inauguration ceremony for B. Pharm and Pharm. D at Srinivasa Mahal on 21.11.2024.



Observed World AIDS Day at VPCW Seminar hall on 29.11.2024. Performed activities like candle lighting, red ribbon campaign and pledge wall to enhance awareness, educate about HIV/AIDS prevention, and offered support to those affected.



Department of Pharmaceutics organised a webinar on “Formulation development of modified release dosage form for improving clinical outcome” by Dr. Gowamma Byran, Associate Professor, JSS College of Pharmacy, Ooty at VIAAS seminar hall on 29.11.2024.



Observed “World Pollution Prevention Day” on 03.12.2024 at VIAAS Seminar hall. Students involved in activities like video presentation and pledge to raise awareness about pollution prevention and promote sustainable practices for cleaner environment.



The Christmas and New Year celebration was celebrated on 31.12.2024 at our campus. Marking the festive season with various activities, decorations, and festivities, bringing together students, faculty, and staff to celebrate and usher in the New Year with cheer and togetherness.



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PREVIOUS ISSUES

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