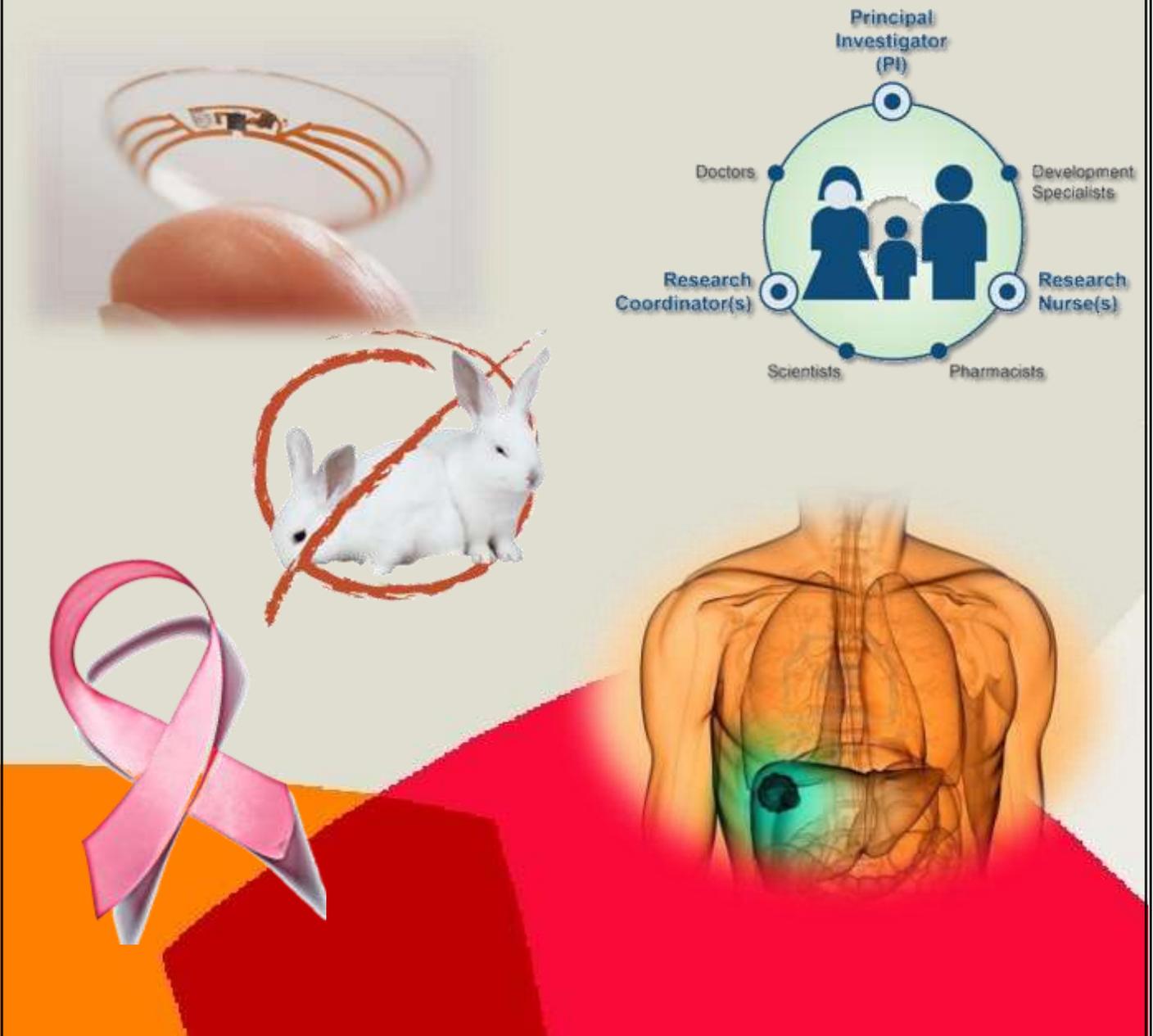


# Aurous Speak

The Quarterly Newsletter from the Corporate of Aurous HealthCare - CRO...

June 2014

Vol.01 Ed.04



**Aurous HealthCare**  
Research and Development India Private Limited  
(Formerly Aurouville HealthCare Research & Development Pvt Ltd)

*The pioneer Contract Research Organisation (CRO) with focus on Clinical Research*

**Since 2008...**

PROPRIETARY OF AUROUS HEALTHCARE R&D INDIA PRIVATE LIMITED  
© Aurous HealthCare R&D India Private Limited, 2008. All Rights Reserved

## *From the Desk of MD...*

We wish Our Honorable Prime Minister Narendra Modi ji the very best in his endeavors for India!!!

A change in the governing bodies always brings about a domino effect on many aspects of our lives.. Healthcare being the most important.

In the quarter that passed by, we have seen, heard and noticed changes that moves towards much accelerated and comprehensive moves to strengthen the medical research field as it stands today.

Ethical concerns have moved up a notch with the ban of cosmetic testing on animals. Medical research continues to see gradual and steady acceptance among people of all strata. New regime has hinted on changes and streamlined process that would provide the much required breathing space for clinical research in India right now.

This edition of **A urouSpeak** comes to you on the first of July. **DOCTORS DAY** - a day that holds special meaning to me. As doctors, many find satisfaction in the recovery of a patient, the sigh of relief and smiles from the family. But there are also many who have taken the chance to walk the extra mile - service and medical research.

At **Aurous HealthCare CRO**, we have invested renewed energy and ideas into both service and medical research - hoping to share more progress and updates with you by the next quarter. To all my fraternity in the medical field - **Happy Doctors Day! Keep up the Great work!!!**

With Best Regards,

**Dr. VT. Sriraam MBBS MD (Pharmacology)**

Managing Director | Medical director – Aurous HealthCare– CRO

Dr. VT. Sriraam MBBS MD (Pharmacology) is the founder– director of Aurous HealthCare - CRO.

An alumni of Stanley Medical College, he was honored as **“The Best Doctor” by the Ministry of Health, Maldives** at the age of 23.

Gaining rich and varied experience at top CRO, Dr. VT. Sriraam founded Aurous HealthCare in 2008. An astute medical entrepreneur, his sharp business sense combined with his rich knowledge and experience in the field of clinical research has pushed Aurous HealthCare from strength to strength.

**Dr. Sriraam has been recognized with “Indian Leadership Award for Healthcare Excellence”**

A man with strengths so varied and unique, Dr. VT. Sriraam is the epitome of the entrepreneurial combination of business brains and clinical-research creatives.



## New Trial Promises Painless Breast Screening

A lump in the breast gives the scare to any woman, but many avoid or postpone screening because mammogram, the only process now available to confirm the presence of a tumour, is a painful exercise. In a few months, at least four hospitals in Chennai will offer a painless alternative - on a trial basis - that uses infrared beams and thermal energy without compressing the breast.

Doctors say it would encourage more women to screen for growths and hence nip breast cancer in the bud. What's more, the new procedure would be more accessible and affordable. Two years ago, the Indian Council of Medical Research approved a multi-centric study in six cancer hospitals across the country, but the study never took off. But now, another wing of the government, the department of biotechnology has given financial sanction for clinical trial after making seven prototypes of the device.

"We have a simple screening protocol that can be used for mass screening anywhere including rural areas. If we prove that this is as efficient as a mammogram, we will be able to diagnose breast cancer at very early stages," said radiologist Dr Sandeep Jaipurkar, who was part of the pilot study in 2011 to test the device.

Breast cancer is one of the most common cancers among women and the first common cause of cancer-related deaths in most cities. It affects at least one in eight women sometime in their lifetime. Oncologist Dr V Shantha of Cancer Institute, Adyar, says that early detection is a vital component in the successful treatment of breast cancer. "Mammograms may be painful and cumbersome, yet they play a central part in early detection of breast cancer because they can detect changes in the breast that may be early signs of cancer. So far we have not seen a successful substitute. It would be good to have one," she said.

The device was initially developed by bio-medical engineers of a company called Puscano Equipment and radiologists from Vijaya Health Centre, Chennai. The patient is made to lie down and an infrared camera below screens the breast thoroughly, without radiation. It captures any abnormal lesions on the breast. Dr Jaipurkar says that when blood flows to abnormal breast tissue, the area around such tissue gets warmer by one to three degrees Celsius, making it a 'hot spot.' The infrared camera picks up the abnormal tissues - such as cysts or tumours - based on this heat difference. Infrared cameras used earlier were ineffective as they took only the frontal image of the breast and missed lumps on the sides and below. But this camera is mounted on a trolley to make a full circle, says biomedical engineer Kannan Neelakantan.

*Continued on page 4...*



### Inside...

*AURO Ayur.....Page 4*

*Know your Diabetes Drug.....Page 5*

*AURO BYTE.....Page 5*

*Congrats Dr. VT. Sriraam.....Page 6*

*USFDA Commissioner visits.....Page 7*

*New Approach to Trials.....Page 7*



**AurouSpeak**  
in your INBOX !!!

*Send a test mail and receive quarterly updates on Clinical Trials and Drug Research in your inbox!*

*mgr.bd@auroushealthcare.com  
corporate@auroushealthcare.com*

**Register!**

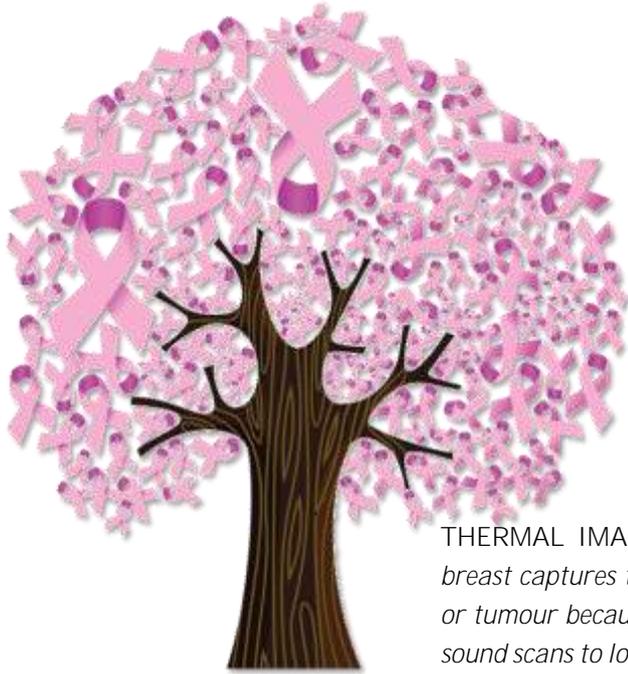


## New Trial Promises Painless Breast Screening

Continued from Page 3...

However, doctors say that the thermal imaging gives only physiological information which has to be combined with an ultrasound for anatomical information. "If the thermal imaging and ultrasound show positive for breast cancer, we send the patient for biopsy. We can do mammography only when the patient insists or if the doctor wants another confirmation," he said. In the past two years, gynaecologists at Vijaya Health Centre has screened more than 1,800 women. After a physical examination, the patients undergo thermal and ultrasound tests. "There were two breast cancer cases for every 300 women screened. Some women who had slight temperature variance were asked to come again after six months and they came back. If it was a mammogram, they would not have come back, even if we offered a 50% discount," he said.

Puscano has patented the triple assessment screening technique and will build seven prototypes in the next few months, Neelakantan said. "We have financial sanctions, but we are waiting for the final clearance from the ministry," he said. He is hoping that they would be able to use the technology for diagnosis of other diseases such as complications of diabetes and eye diseases.



**THERMAL IMAGING AND ULTRA SOUND:** A camera that revolves around the breast captures the 'hot spots'. Temperature varies in spots where there is a lesion or tumour because more blood rushes around it. This test is combined with ultrasound scans to look for anatomical changes.

**ADVANTAGE:** Considered cost effective, painless, accessible technology

**DISADVANTAGE :** Yet to be tested and standardized, still under trial .

## AURO Ayur...

Indrayava (seed)...

Scientific name: Dried Seeds of *Holarrhena antidysenterica*

Sanskrit : Bhadra Yava, Kaliga, Assamese : Dudhkuri; Bengali : Kurchi; English : Ester Tree, Conessi Seeds

Gujrati : Kuda, Kudo; Hindi : Indrajau, Kurchi, Kuraiya; Kannada : Kodasige Beeja; Malayalam : Kutakappala

Punjab: Indrajau; Tamil: Kudasapalai; Telugu: Kodisapala Vittulu ; Urdu: Tukhm-e-Kurchi

Medicinal uses:

In Ayurveda and Unani system of medicine it is used as Antihelmintic, for diarrhea and skin disease.

Ayurvedic Properties and Action:.

- Rasa: Katu, Tikta
- Guna: Laghu, Rukha.
- Virya: Sita
- Vipaka: Katu
- Karma: Dipana, Sangrahi, Tridosha samaka

Dose: 3-6g (Curna) 20-30g (Decoction)



Ref : Ayurvedic pharmacopeia of India Part-I Volume-III: Shah et al. International Journal of Phytomedicine 2 (2010) 345-348.

## **DIABETES DRUGS DO MORE HARM THAN GOOD FOR OLDER PEOPLE...**

Treatments to reduce blood sugar levels do more harm than good in many type 2 diabetes patients, particularly older people. This is the eye-catching conclusion of research from University College London, the University of Michigan and the Ann Arbor Veterans Affairs Hospital.

A study, published in *JAMA Internal Medicine*, found that for many people the benefits of taking diabetes medications “are so small that they are outweighed by the minor harms and risks associated with treatment”. The researchers argue that the benefits of treatment decline with age and indeed the risk outweighs those benefits by the age of 75. They argue that it depends less on their blood sugar level than their age “and the hassles and side-effects of the treatment”. Their claims are based primarily on a 20-year study of type 2 diabetes treatments involving 5,102 people in the UK, where people with an A1c above 6.5% can be diagnosed with diabetes.



The researchers looked at how effective diabetes treatments were at preventing associated complications, such as kidney, eye and heart disease in tandem with the increased risk of side-effects and the burden of taking pills or injections. John Yudkin of UCL and co-author of the paper, said that a typical person with type 2 diabetes who begins treatment at age 45 and reduces their A1c by 1% “may gain up to ten months of healthy life. At age 75, they may gain as little as three weeks of healthy life. Whether this is worth 10-15 years of pills and injections with potential side-effects is ultimately up to the patient”.

He added that “ultimately, the aim of a treatment is not to lower blood sugar for its own sake but to prevent debilitating or deadly complications,”. If the risk of these complications “is suitably low and the burden of treatment correspondingly high, treatment will do more harm than good. The balance between the two can never be defined by a simple figure like blood sugar level”.

Lead author Sandeep Vijan, Professor of Internal Medicine at the U-M Medical School, agreed, saying that “if you’re having low blood sugars, gaining weight or find frequent insulin shots to be disruptive to your daily life – all for minimal health benefits – the drugs are doing more harm than good”. Commenting on the study, Simon O’Neill, director of health intelligence at Diabetes UK, noted that “clearly, everyone with type 1 diabetes needs to have insulin to stay alive” but for type 2, sometimes there is a balance to be struck where certain medications might help give someone a longer life but also cause side effects that might negatively impact on quality of life.”

He added that the study “highlights the importance of looking at the individual needs of the person with type 2 diabetes, rather than adopting a blanket approach”.

## **AURO Byte..**

### **KEGG: Kyoto Encyclopedia of Genes and Genomes**

[www.genome.jp/kegg/kegg1a.html](http://www.genome.jp/kegg/kegg1a.html)

KEGG started in 1995 is a “computer representation” of the biological system. KEGG is widely used as a reference knowledge base for integration and interpretation of large-scale datasets generated by genome sequencing and other high-throughput experimental technologies. In addition to maintaining the aspects to support basic research, KEGG is being expanded towards more practical applications integrating human diseases, drug and other health related substances.

KEGG consists of 15 main databases categorized into systems information (PATHWAY, BRITE and MODULE), genomic information (ORTHOLOGY, GENOME AND GENES), chemical information (COMPOUND, GLYCAN, REACTION, RPAIR, RCLASS and ENZYME) and health information (DISEASE, DRUG and ENVIRON). The chemical and health information categories are collectively called KEGG LIGAND and KEGG MEDICUS respectively.



We are proud and happy to announce that  
Our Beloved Founder-Managing Director

**CONGRATS SIR!!!**

**DR.VT.SRIRAAM** MBBS MD (PHARMACOLOGY)

has been recognized with the

**"INDIAN LEADERSHIP AWARD  
FOR  
HEALTHCARE EXCELLENCE"!!!**



**'LARGEST EVER' TRIAL OF ADULT STEM CELLS  
IN HEART ATTACK PATIENTS BEGINS...**



The stem cell trial - titled "The effect of intracoronary reinfusion of bone marrow-derived mononuclear cells (BM-MNC) on all-cause mortality in acute myocardial infarction," or "BAMI" for short - **has been made possible due to a €5.9 million (\$8.1 million) award from the European Commission.** The full study involves 19 partners across France, Germany, Italy, Finland, Denmark, Spain, Belgium, Poland, the Czech Republic and the UK. A total of 3,000 patients will be involved in the trial to test whether life can be prolonged by administering stem cells from the patient's own bone marrow. The stem cells are injected into the patient's heart within 5 days of suffering a heart attack. The doctors behind the study hope that this could increase heart attack patients' survival rates by 25%. "This trial brings together a powerful partnership of European doctors and scientists to solve a fundamental problem of importance to all people," says Prof. John Martin, from University College London - one of the partners in the trials. "It will give an answer about whether adult multi-potential stem cells in their natural environment can treat human disease." BAMI follows in the steps of three stem cell trials titled "REGENERATE." These trials, conducted by Barts Health NHS Trust in the UK, have been running for 4 years thanks to funding from the charities Heart Cells Foundation, The UK Stem Cell Foundation and Barts Charity. The REGENERATE trials use bone marrow stem cells to treat patients with ischemic heart disease, acute myocardial infarction and heart failure caused by idiopathic dilated cardiomyopathy. Founder and trustee of Heart Cells Foundation, Jenifer Rosenberg OBE, comments: "On behalf of my fellow trustees and those who have so generously donated to our foundation, I am hugely proud that our own REGENERATE trials have paved the way for this new important European trial." "The BAMI study is the biggest and most comprehensive trial of its kind in the world," adds trial chief co-ordinator.

### **CLINICAL TRIAL MANAGEMENT** for Herbal Products - Herbaceuticals & Medicines, Nutraceuticals, Cosmeceuticals.

We specialise in conducting **END to END** clinical trial projects.

We cover the entire project from **Conception, Study Design, Medical Writing, Project Management, Regulatory Approval, Conduction Of The Clinical Study, Data Management, Statistical Analysis & Report Preparation!**



### **ANIMAL TOXICITY & SAFETY STUDIES** exclusively for Herbal Medicines of **AYURVEDA** and **SIDDHA**.

Our expertise in handling **ANIMAL TOXICITY** studies as well as **CLINICAL TRIALS**, gives **YOU** the **UNIQUE ADVANTAGE** of an **R&D Partner**, who is with you... with your product... from safety testing all the way upto marketing!



**Contact : mgr.bd@auroushealthcare.com +91-9840909155**

We also offer **Clinical Trial Rescue Services** to help mend strained Sponsor—CRO relationships, issue analysis at Clinical Trial Site, Medical monitoring services and independent quality audit services.

**AURO Quiz.. Ayurveda . . .****Match the disease with the English equivalent...**

- |                    |                         |
|--------------------|-------------------------|
| 1. Greevagraham    | A. Vomiting             |
| 2. Sidhmam         | B. Cough                |
| 3. Chardi          | C. Cervical Spondylosis |
| 4. Kasa Roga       | D. Diabetes Mellitus    |
| 5. Rakthadi Mardam | E. Psoriasis            |
| 6. Prameham        | F. Hypertension         |

Next Edition: How well do you know *History of Clinical Trials??*

Answers on Page 4

**More from AURO-BLOG...**

- Dr.Harsha Vardhan and his plans for the Pharma Industry
- Ban on testing of Cosmetics on animals.
- Several bills on hold at the Parliament. Hopes on new government for better and streamlined processes.
- TN Govt opens "Amma Pharmacy"
- Clinical trials in India: Narendra Modi govt plans to clip wings of drug regulator
- FDCs licenced prior to Sept 21, 1988 excluded from proving safety, efficacy to DCGI
- ICMR issues 'Criteria for Dental Fluorosis'
- Apex panel on clinical trials gives nod to 21 fresh proposals
- New model proposed for clinical trials – E2E trials.
- FDA approves first human papillomavirus test for primary cervical cancer screening

Details of these posts and more on

[www.auroushealthcare.wordpress.com](http://www.auroushealthcare.wordpress.com)

**NEW APPROACH TO CLINICAL TRIALS COULD BOOST PARTICIPATION...**

It's a classic Catch-22: medical researchers need to figure out if a promising new treatment is truly better than a current one, by randomly assigning half of a group of patients to get each treatment. But when they approach patients about taking part in the study, those 50-50 random odds don't sound good enough - and the study struggles to get enough volunteers. That slows down the effort to improve treatment for that condition.

Now, new research shows the promise of an approach that takes some of the "random" out of the process, while preserving the ability to compare treatments. Instead of every patient getting a randomly chosen treatment, the approach adjusts the odds as the study goes along. So if early results show that one of the two treatments appears to work better, each new patient's odds of getting that treatment increase. It's called response-adaptive randomization, or RAR.

In a new brief report in the journal *Stroke*, University of Michigan Medical School researchers report the results of how 418 emergency department patients responded to the two approaches to medical studies. The researchers asked the patients to imagine they had just suffered a stroke, showed them a video describing a study that needed stroke patients, and asked them whether they would volunteer for that study if they had really just had a stroke. What the patients didn't know is that half of them had randomly been shown a video that described a classic randomized study, and half had seen the same video but with an added section explaining that if one treatment appeared to be working better in earlier patients, their odds of getting it would improve.

Only 54 percent of the people shown the first video said they would volunteer for the study. But 67 percent of those shown the RAR video said they'd enroll. If the results play out in real emergency stroke studies, this 13-point difference could make a big difference in the pace of medical research, says William Meurer, M.D., M.S., the U-M **emergency physician who led the study**. "Although this is a hypothetical scenario, it shows we might increase recruitment for acute stroke studies using a response-adaptive randomization design," he says. "This could be especially important in emergency situations, when patients or their loved ones have just minutes to consider options." The new study has already led to further research that will look at patients' comprehension of the explanation of their odds of getting one treatment versus another.

The main challenge in doing RAR studies comes in making sure that the researchers gather enough data about each treatment to make their findings statistically sound - that is, to be able to tell for sure that the differences between treatments are real and not due to chance. They're also surveying clinical trial researchers about what they think of the RAR approach. Barsan says, "We think that using the RAR approach is very appealing in our network, where we are treating patients with life-threatening neurologic emergencies such as stroke and head trauma. Knowing that more patients will receive the more effective therapy just seems like the right thing to do." Performing an RAR study does require more infrastructure and preparation for researchers, Meurer says - for example, instead of just making up equal numbers of treatment packs when the study begins, the research team must prepare increasing numbers of packs containing the option that's working better.

Ref : Medical News Today.



# Auro Speak

[www.auroushealthcare.wordpress.com](http://www.auroushealthcare.wordpress.com)

The Quarterly Newsletter from AHC - CRO

Subscribe : Send an email to [mgr.bd@auroushealthcare.com](mailto:mgr.bd@auroushealthcare.com) today...



THE PIONEER CONTRACT RESEARCH ORGANISATION (CRO) WITH FOCUS ON CLINICAL RESEARCH

---

AUROUS HEALTHCARE RESEARCH AND DEVELOPMENT INDIA PRIVATE LIMITED  
(Formerly Auroville HealthCare R & D India Pvt Ltd.)

#180/109, Rangarajapuram Main Road, Kodambakkam, Chennai-600024.

Phone: +91-44 23720600, +91-44 32472446 • Mobile: +91 9551050612 Fax: +91-4423720600

[contact@auroushealthcare.com](mailto:contact@auroushealthcare.com)

[mgr.bd@auroushealthcare.com](mailto:mgr.bd@auroushealthcare.com)

[www.auroushealthcare.com](http://www.auroushealthcare.com)