February 2020

DHRHealth Institute for Research & Development
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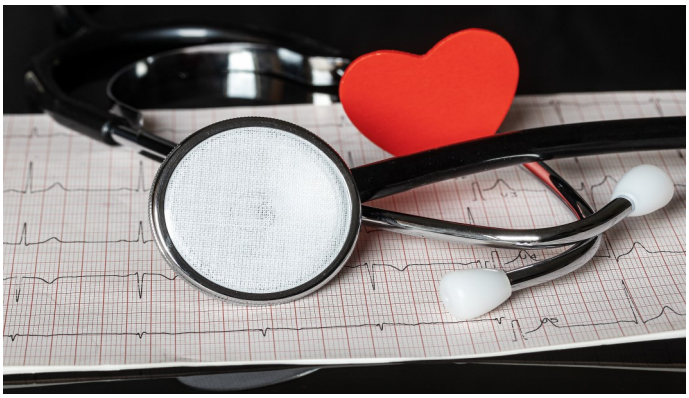
The Research Spectator

A Phase 3 Study Aims to Find New Long-Term Treatment Option for Lowering Cholesterol

In 2017, the DHR Health Institute for Research and Development became a site for ORION 10 – a randomized, phase 3 study, aimed to evaluate the effect of ***Inclisiran Sodium*** given as a subcutaneous injections in subjects with atherosclerosis cardiovascular disease and elevated low density lipoprotein cholesterol (LDL-C).



Atherosclerosis cardiovascular disease (ASCVD) is a disease in which plaque builds up in the arteries. This plaque contains fat, cholesterol, calcium and other substances. As more plaque begins to build up, and hardens, it narrows the arteries that carry oxygen-rich blood to the body's organs. When left untreated, ASCVD can lead to heart attack, stroke, or even death. Among Hispanic adults, almost every 1 out of 2 men, and every 1 out of 3 women have cardiovascular disease.

A highly used treatment for ASCVD is lifestyle modification and a statin to help lower lipid levels. ***Inclisiran*** is a small interfering RNA therapeutic that inhibits production of PCSK9 in the liver, and offers a novel modality to further reduce LDL-C in patients at high ASCVD risk after treatment with statins and other agents.

Participants in this study were randomized into one of two groups, one of which would receive 300 mg of ***Inclisiran*** as a subcutaneous injection, and the other would receive a placebo. These injections were only given twice a year. Key findings from the study showed that the ***Inclisiran*** injections were highly significant in lowering LDL-C levels, relative to the placebo. The percentage change in LDL-C for participants who received Inclisiran was –51%, while those on the placebo, showed an increase of +1%.

In 2019, ORION 8, an extension of ORION 10, was started at DHR Health Institute for Research and Development. The same participants from ORION 10, regardless of whether they received ***Inclisiran*** or the placebo, were enrolled to participate. In this new study, there is no placebo, so all participants will receive a subcutaneous injection of ***Inclisiran*** over the course of three years. The goal of this study is to evaluate the efficacy, safety and tolerability of long-term dosing of ***Inclisiran.***

New Electronic Smart Form is Launched on IRBNet to Facilitate the IRB Submission Process

To create a more efficient study submission process on IRBNet, the DHR Health Institute for Research and Development has launched a smart application form for investigators. This electronic application is to be used by investigators when a new study is being submitted to the IRB. Investigators no longer will have to download the study application word document, fill it out, and then re-submit it via IRBNet.

The application is to be used for all study review types, as investigators will indicate the type of review they are applying for. The questions will be generated based on the type of review that is selected. All required fields must be completed before submission.

Once the application is complete, the system will indicate if there are any supplemental documents that need to be submitted based on the responses provided by the investigator.

The goal of the smart application is to decrease the amount of time it takes to complete the application, and ensure that all of the required information is included for timely IRB review.

IRBNet
www.irbnet.org

Mahesh Changlani, MD
Cardiologist

Dr. Mahesh Changlani is a cardiologist, and Clinical Research Scientist, Research Academy at DHR Health Institute for Research and Development. Dr. Changlani received his medical degree from Seth G.S. Medical College in Bombay, India. He completed an internship and residency training at Cook County Hospital in Chicago, Illinois. Dr. Changlani then continued his education at Michael Reese Hospital, University of Illinois with a fellowship in cardiology .

Dr. Changlani has held previous positions at Lakewood Medical Center, Dauterive Hospital, and Cardiovascular Institute of the South. He also served as an Assistant Professor of Cardiology at the University of Alabama at Birmingham. Currently, Dr. Changlani is a cardiologist at DHR Health and serves as Chairman on the DHR Health Institute for Research and Development Institutional Review Board.

He has extensive experience in research as a principal investigator in various trials in the fields of atherosclerosis, coronary artery disease, congestive heart failure, hypertension and other. Dr. Changlani is currently a part of four active trials at the DHR Health Institute for Research and Development.

The Rio Grande Valley's First Scientific Journal is Launched at DHR Health

The DHR Health Institute for Research and Development is proud to launch the first scientific journal in the Rio Grande Valley entitled *DHR Proceedings. This journal will be one of the premier peer-reviewed health sciences journals in general and specialty medicine.* The main goal of DHR Proceedings (DHRP) is to publish articles that focus on cutting-edge and innovative strategies that generate new knowledge and enhances the experience of its readers. It is also the goal of DHRP to highlight healthcare disparities observed in the Hispanic population, particularly in South Texas. We invite submissions from authors in the region and nationally. The Journal will consider manuscripts for publication in the following categories: Commentaries, Brief reports, Research Manuscripts, Case Studies, Review Articles, Health Care Policy and Economics, Medical Education, Laboratory Medicine, and Ethics. *DHR Proceedings* will be published quarterly as an online-only format. In this format, we will be able to post supplemental material and videos related to individual articles. DHRP has received the International Standard Serial Number (ISSN): 2689-839X. During its first year of publication, we will seek indexing in PubMed. For more information, you can access the journal web page at www.dhrproceedings.org or contact the inaugural managing editor, Dr. Torres-Reveron, at 956-362-2392 or 956-638-1501. You can also send us an e-mail at info@dhrproceedings.org.

DHR Proceedings

DONATE

Let Us Work Together to Eliminate the Burden of Chronic Diseases in the Rio Grande Valley

The emergent challenge for the community in the Rio Grande Valley is the high incidence of key chronic diseases including Diabetes, Obesity, Cardiovascular Diseases, Non-alcoholic Fatty Liver Disease, Cancers and others. Further compounding this observation is the fact that a growing number of people are uninsured and therefore unable to access quality healthcare in a timely manner. Partnership with the community to is the only possible way in which we could address this burgeoning challenge.

DHR Health Institute for Research & Development is a nonprofit 501(c)3 entity organized under the Texas Nonprofit Corporation Act. It is largest and the most comprehensive clinical research organization in the Rio Grande Valley, and this has been possible with your kind support and active engagement. Your generous gift will empower DHR Health Institute for Research & Development to continue to serve the community and bring state-of-the art advanced clinical care for the residents of the Valley.

Our Community Needs Your Support…Donate Generously By Going To This Website:
https://dhrresearch.org/donate/

What are the three different types of IRB study review?

February 2020

Institutional Review Board Meeting
February 26, 2020 | 12:30 PM
DHR Health Institute for Research and Development Collaboration Room | 5323 S. McColl Road, Edinburg, TX

Before any clinical research study can be activated, an investigator must first submit their protocol to DHR Health Institute for Research and Development Institutional Review Board (IRB) to ensure that the rights and welfare of study participants are protected.

Exempt Review— The name of this type of review can be misleading as studies that meet the "exempt" criteria do require IRB review and registration. There are eight (8) exempt categories that have been defined by the Office of Human Research Protection (OHRP), Department of Health & Human Services (DHHS). Studies that meet the exempt criteria entail the lowest level of risk to potential participants and can be submitted at any time for IRB review and registration. IRB approval for exempt review studies does not expire.

Examples

- Studies collecting anonymous or unidentifiable surveys or interviews
- Studies involving passive observation of public behavior with or without the collection identifiers
- Studies involving the analysis of specimens that are publically available or if not publically available,
  where the identities of the subjects cannot be readily ascertained

Expedited Review—This is another type of review for studies at DHR Health. And while the title might indicate a quicker review process, these studies follow a similar timeline as the other two review types. For a study to qualify for an expedited review, it must meet the requirements for one of the nine (9) categories defined by OHRP, DDHS. Studies meeting expedited review criteria do not need to be submitted by a certain date in order to be reviewed. Additionally, IRB approval for expedited review studies does not expire and as such, continuing review is not required.

Examples

- Studies of existing pathological specimens or data with patient identifiers
- Studies of blood samples from healthy volunteers
- Studies involving the collection of identifiable information in surveys. Interviews, or focus groups.

Full Board Review—Studies that require a full board review, are those that involve greater than minimal risk to the participants. Studies will also require full board review if they involve children under the age of 18, prisoners, individuals with impaired decision-making capacity and procedures that may cause physical harm or significant psychological/emotional distress to the subject. Studies requiring full board review must be submitted to the IRB by the monthly submission deadline to ensure it will be included on the agenda for the next convened meeting. IRB approval for these studies is granted for a determined length of time not to exceed one year. Continuing review is required for re-approval if the study is too continue beyond the indicated expiration date.

Examples

- Studies involving prospective clinical trials and/or clinical intervention
- Research that involves the use of medical devices (in most cases)
- Studies that involve participant deception (e.g., placebo control studies.

For more information, please visit: https://www.hhs.gov/ohrp/.

Team Spotlight: Karla S. Asian-Rojas

Karla received her undergraduate nursing education from Universidad Peruana Cayetano Heredia–Peru. In 2012, she started working at Harold Simmons Cancer center at UTSW in Dallas in the oncology research area. In 2014, she became part of the Texas Children's Hospital team as a research nurse. Karla is experienced in investigator initiated trials, Phase I through Phase IV studies in oncology, gastroenterology, cardiology, and most recently NICU. At the DHR Health Institute for Research and Development, Karla is part of the Border Biorepository at DHR team and oversees the cardiology studies.

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