

INSIGHTS INTO CLINICAL TRIALS



Over the years medical research has advanced our knowledge of medicine. Treatments for various diseases and illnesses are now available because of research studies. While advancements are welcomed by most, not so is the ability to take that leap of faith and sign up for a research study. Fear, misinformation and lack of trust may keep patients and volunteers from helping advance the knowledge of medicine and treatments.

At the forefront of worldwide research is Dr. Narendra Singh, board certified cardiologist and Director of Clinical Research with Atlanta Heart Specialists, LLC. He leads a nationally and internationally recognized research team based out of Cumming Georgia.

“Clinical trials are the cornerstone to medical progress and we are excited to offer these opportunities to our community” stated Dr. Singh. Clinical

trials look at new ways to prevent, detect, or treat disease. Treatments might be new drugs or new combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments.

“The goal of clinical trials is to determine if a new test or treatment works and is safe. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses,” Dr. Singh added.

Clinical Trials Research *Should I participate?*

Informed consent is essential to performing high-quality research. The investigator should be able to explain to you what the study is about, who is doing it, what are the risks, benefits and alternatives, what the safeguards are, and how your privacy is protected. All quality research is overseen by an institutional review board

(IRB) and a data and safety monitoring board (DSMB) who provides independent oversight to ensure that the work is conducted to the highest ethical standards.

“Participating in a clinical trial gave me the opportunity to play a role in the discovery of treatments, cures, and preventions for certain diseases or medical conditions,” explained Daniel G., patient.

While payment to participate in research is not considered ethical, our practice is able to compensate you for all travel related costs and there are no additional expenses to you or your insurance company.

Research also has a potential to provide the



Dr Singh has been a site investigator in over 100 national and international trials. He actively designs and conducts independent research. He has published extensively on topics ranging from South Asian heart disease, acute coronary syndromes, health outcomes, and disparities in access to care. He is the recipient of numerous awards and a highly sought after speaker and educator.

Clinical trials are the cornerstone to medical progress...

terms of more diligent care, early access to a new drug or device and free medical evaluations with a specialized team. It's one of the reasons why patients who participate in clinical trials usually do better than patients outside of trials regardless of which treatment arm they are assigned.

In clinical trials there is often a placebo (standard of care) arm. The purpose of this blinded random assignment to active treatment versus placebo is to reduce the possibility of introducing bias regarding the effect of the new intervention. In addition it is well known that the power of suggestion has a large therapeutic effect and therefore must be balanced.

Many of the drugs and devices that we now take for granted would not have been available had it not been for clinical trials research.



“Only with research did we find that a drug as simple as aspirin used previously for pain control, actually improved survival during a heart attack,” Dr. Singh added.

The Phases of Research

Research is conducted in phases. Phase I studies are the first exposure in humans and carry with them the greatest risk or uncertainty. Phase II studies are small and designed to see if the experimental agent is beneficial.

Phase 3 studies are the large clinical trials that determine whether the drug should make it to market. Phase 4 studies take the approved compound and look for new indications for its use and are usually the safest of the trials.

“Being involved with research for the past 20 years and working with an outstanding team of highly experienced certified research coordinators and physicians I encourage you to consider involvement when the opportunity arises. You don't



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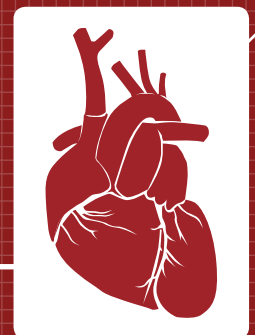
Meet Dr. Narendra Singh

Dr. Singh is a Fellow of the American College of Cardiology, American Heart Association and Royal College of Physicians and Surgeons of Canada. He is a Clinical Assistant Professor at Georgia Regents University and Director of clinical research within his group. He is a Clinician Scientist with the Canadian

Cardiovascular Research Network. Dr Singh also serves as a councilor on the Georgia Chapter, American College of Cardiology board.

heartdrsingh.com

678-679-6800



Clinical trials provide participants with an opportunity to help people suffering from medical conditions.



Research Team - Left to Right: Shraddha Dubal, Denise Whitlock, Gulanara Gousseinova, Erin Hampton, Courtney Clark, Kati Turner, absent-Deb Logwood

Clinical trials often come with hard to pronounce names but cover a wide range of conditions such as diabetes, high cholesterol, heart attacks, atrial fibrillation, heart failure, pacemakers, inflammation and peripheral atrial disease. If you would like to learn more about eligibility you can contact us at 678-679-1065 or e-mail DrSingh@heartdrsingh.com

Atlanta Heart Specialists studies open to enrollment: Cantos, Reduce-It, Odyssey Outcomes, Grand, Gloria-AF, CIRT, Siello, Declare Paragon HF, Tigris, Orbit AF Registry.

They are a nationally and internationally recognized research team based out of Cumming, Georgia.

even have to be a patient in our practice as long as your other physicians agree to your participation” stated Dr. Singh.

Each clinical trial in the United States must be approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are minimal and are worth any potential benefits. An IRB is an independent committee that consists of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are

protected. Federal regulation requires all institutions in the United States that conduct or support biomedical research involving people to have an IRB initially approve and periodically review the research. Atlanta Heart Specialists has 10 other cardiologists in 7 locations throughout the city and a second research facility based out of the flagship office in Tucker, Georgia.

To learn more about trials at Atlanta Heart Specialists, LLC visit www.heartdrsingh.com or nationally at www.clinicaltrials.gov.