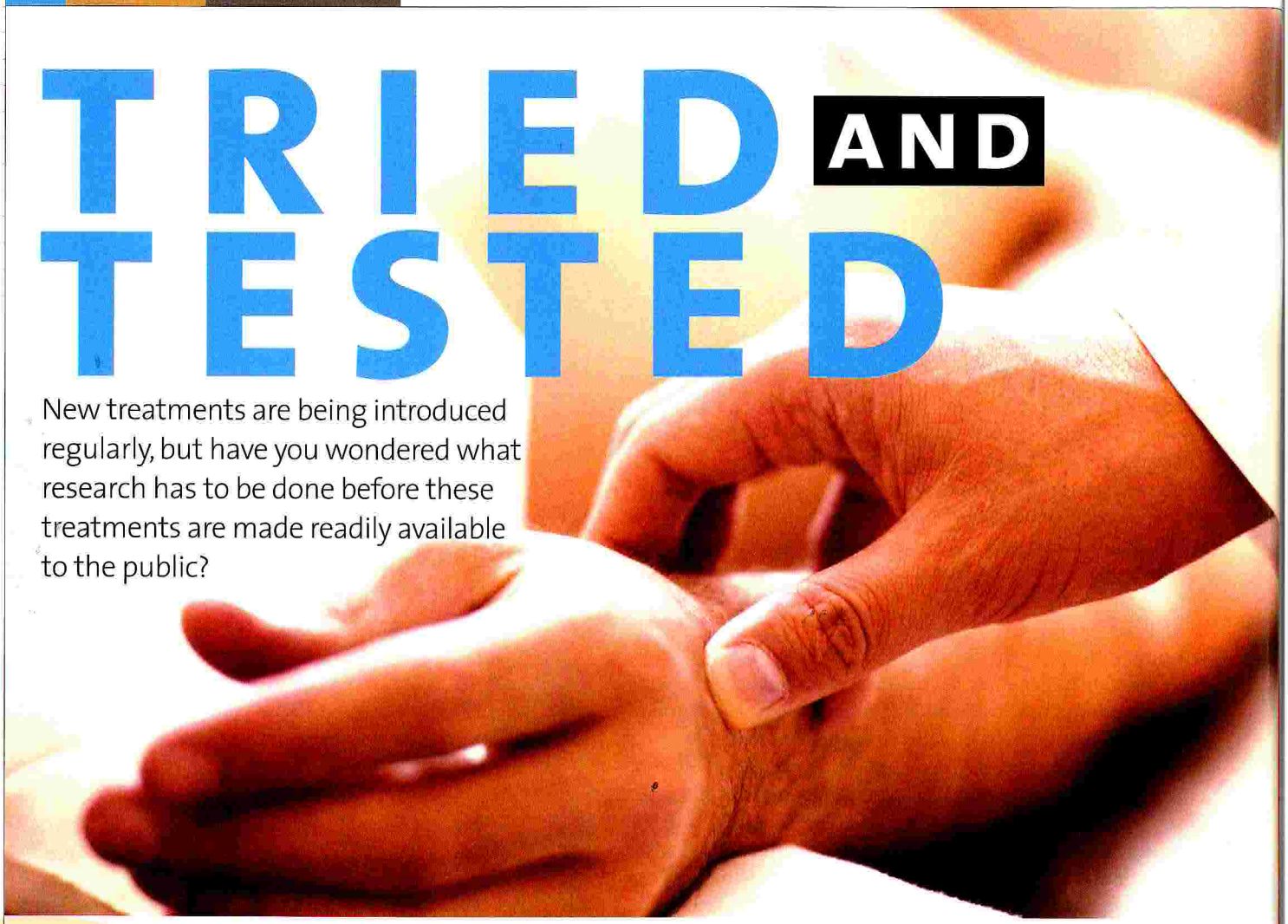
FEATURE

TRIED AND TESTED

New treatments are being introduced regularly, but have you wondered what research has to be done before these treatments are made readily available to the public?



art of the research process into the development of a drug or procedure requires human participation, through what are called Clinical Trials. So what are clinical trials, how can you get involved in one, and what should you find out before deciding whether or not to participate?

Lifewise speaks to Dr Goh Boon Cher, Senior Consultant (Haemotology-Oncology) at the National University Hospital (NUH), and Dr Allan Harkness, Dean of the Asia Graduate School of Theology and a lay member of three Singapore medical ethics committees, to find out more about this topic.

Q: What are clinical trials?

A: A clinical trial is a research study conducted with participation of people who volunteer to participate, with the aim of answering questions that doctors have regarding specific health questions. You can think of it as a research study with human volunteers.

Q: Why have clinical trials?

A: You might wonder why clinical research trials are needed. Well, there are a number of reasons for clinical research trials to be done. These include:

- Comparing existing treatments to find out which is more effective
- To find out new ways to make existing treatments more effective, or to find ways to cut down the side effects of these treatments
- To find out if new drugs or devices are safe and effective for human use
- To find ways to improve the quality of life for people who have serious medical conditions

With information gathered from clinical trials, doctors and researchers can find more effective treatments for their patients.

Q: Why should I consider taking part in clinical trials?

A: A clinical trial is one way to get access to new, investigational treatments, whether they are drugs, medical devices or procedures, before they are widely available. "Participants can also feel they have more control over their situation, and are taking a more active role in their health care. They are also helping others by contributing to clinical research," Dr Goh says.

BY **EVELYN MAK**

Q: Who can participate in a research study?

A: Each research study has specific criteria about who can participate, known as eligibility criteria. Eligibility criteria are based on factors such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. The investigator will assess this carefully before one can be entered into a research study.

Q: Are there any risks involved in participating in clinical trials?

A: As with any kind of drug, device or procedure, there are risks involved. For example, the drug/device/procedure may have unknown side effects which may or may not be worse than the side effects of available treatments. The treatment may not work (at all, or to a certain extent) for the participant, or may even worsen the medical condition.

To lessen the risk to the participant, as well as to get the most accurate result from the trial, Dr Goh strongly suggests that participants be responsible for their commitment and actions when agreeing to participate in a trial. "They should follow the directions given by the Principal Investigator, like taking medication promptly, and returning for follow-up visits. They should also inform investigators of any side effects or changes that they experience truthfully," Dr Goh details.

Q: Will I have to pay to participate in a clinical trial?

A: In a majority of cases, any costs incurred due to non-standard clinical care, such as surgery, transport and medication cost, will be reimbursed to the clinical trial participant. But it's best to confirm this with the Principal Investigator before the start of the clinical trial.

Q; Can I withdraw in the middle of a trial?

A: A participant can leave a clinical trial at any time. "When withdrawing from the trial, the participant should let the research team know about the decision and may offer the reason(s) for leaving the study - although the participant should not be put under any pressure to justify the decision to withdraw, or face any sort of penalty for withdrawing," says Dr Harkness. To ensure that a participant withdraws from the trial safely, the Principal Investigator will advise on proper and safe ways to withdraw from the trial. Additionally, the Principal Investigator may decide to withdraw the participant from the clinical trial for safety reasons.

Q: Is there anyone who monitors clinical trials to make sure that they're being carried out correctly?

A: According to Dr Goh, every clinical trial taking place in National Healthcare Group (NHG) has to undergo rigorous reviews by the Domain Specific Review Board (DSRB), a committee tasked to safeguard the rights, safety and well-being of participants, and to ensure the whole process is ethically acceptable. "Made up of medical experts, non-medical personnel, legal experts and patient advocates, the DSRB reviews the study protocol to ensure that the study is of benefit, and that the risks associated with the trial are minimised," he says. So research participants can be assured of a good informed consent process and continuous monitoring throughout his/her participation in the research. The standard is high: NHG's clinical trials review process was recently accredited by the USA-based Association of the Accreditation of Human Research Protection Programs, Inc (AAHRPP), confirming the quality of its activity.

If participants are not happy with aspects of their participation in a trial, they should raise the matter with the people conducting the trial. Dr Harkness says that sometimes, the issue may just be a misunderstanding that can be easily solved. "However, participants may go to the DSRB overseeing the trial to lodge a complaint, raise issues they feel uncomfortable about or require clarification. The contact details for the DSRB will be stated in the consent document provided to the participants".

WHAT SHOULD YOU ASK YOUR DOCTOR?

BEFORE YOU MAKE THE DECISION TO PARTICIPATE IN A CLINICAL TRIAL, IT'S BEST TO HAVE A CLEAR IDEA OF WHAT THE PROCESS INVOLVES.

Here are some useful questions you could ask your doctor about the clinical trial you're interested in.

- What is the purpose of this study?
- Why do researchers believe the drug/device being tested may be effective?
- Has the drug been tested before? On whom?
- How will the procedures be carried out?
- What are the possible risks and side effects of the treatment being tested? What benefits are there when compared with my current treatment?
- Are there any costs involved? Will I be reimbursed for any expenses incurred?
- Will I need long-term follow up care after the trial? Is this care included in the study?
- What happens if I suffer from a research related injury?
- How long will the trial last?
- How will I know that the treatment is working?
- Will I be able to opt out of the trial midway if I choose to?
- Will my medical records, the process and results of the study be kept confidential?

Q: What happens at the end of the treatment?

A: At the end of each clinical trial, data from each participant will be collected and analysed. The data may also be published in medical journals – in such publications, the identity of patients will be kept confidential. If the data looks promising, researchers may continue with the next level of testing, or file with regulatory agencies to market the treatment.

So what's the most important thing you should remember when you're thinking of participating in a clinical trial? Dr Goh's advice is to clarify all queries you have, such as possible side effects, compensation in the case of any injury arising from being in the trial, reimbursement for expenses, and your responsibilities as a participant. "Find out as much as you can from the doctor in charge. It would also be good to talk through your participation with your family members," Dr Goh suggests.

Dr Harkness has similar advice. "Ask questions until you are satisfied that you feel comfortable enough to take part in the trial," he says.

The NHG will be organising a PUBLIC FORUM ON CLINICAL RESEARCH, where you can learn the bare essentials of clinical research from the perspectives of a doctor, a research participant, and an ethics advisor.

Date: 26 July 2008

Time: 8.30am – noon (Registration and coffee starts at 8.30am)

Venue: TTSH Theatrette Level 1, Tan Tock Seng Hospital (Nearest MRT station: Novena MRT)

Lunch will be provided.

Pre-registration is required. Please call 6496 6964

Organised by the Research & Development Office, National Healthcare Group.

If you are interested to be a research participant, please contact the following:

NATIONAL UNIVERSITY HOSPITAL
Clinical Trial Unit
Tel: 6772 5080

NATIONAL SKIN CENTRE
Clinical Research Unit
Tel: 6350 8582

TAN TOCK SENG HOSPITAL
Clinical Research Unit
Tel:6357 8391

INSTITUTE OF MENTAL HEALTH
Clinical Research Unit
Tel: 6389 2959

NHG POLYCLINICS
Clinical Research Unit
Tel: 6496 6756

For HIV-related research, please contact:
TAN TOCK SENG HOSPITAL
Communicable Disease Centre (CDC)
Tel: 6357 7900/6357 7909

For Cancer-related research, please contact:
CANCER THERAPEUTICS RESEARCH GROUP (CTRG)
Tel: 6772 4619

ONE MAN'S STORY

Lifewise spoke to Mr. Robert Lee, aged 68, who has previously participated in a clinical research trial, to find out more about his experience.

What kind of clinical research trial did you participate in?
I took part in a clinical research study to determine if a particular drug was more effective in preventing a second stroke as compared to another drug.

How did you find out about the trial?
I suffered a stroke in Dec 2004 and was admitted to NUH. During my hospitalisation, the attending doctor informed my family members and me about this clinical study of a drug to prevent a second stroke and offered me the option to participate.

Why did you decide to participate in the trial?
My family members and I were keen since I had just suffered a stroke, and the aim of the trial was to prevent a second stroke. Of course, we still had some reservations about the side effects, risks and benefits of the medication on trial. The doctor and trial coordinator sat us down and explained the purpose of the study, how it would be administered, along with other details. They addressed our concerns and reassured us that participation of this trial was voluntary; that evidence to date suggested the risks were manageable and we would be able to withdraw from the study at any time. After weighing the pros and cons, my family members and I made the decision for me to participate in the trial.

What was participation in your clinical trial like?
It was actually very simple - mainly involving taking regular medication and follow-up visits at NUH every few months. During the first visit, the doctor did several tests (blood pressure, heart rate, urine samples etc.) and gave me the medication, along with instructions on how it should be taken. I was briefed about the possible side effects again, and given the contact numbers of both the doctor and the trial coordinator, whom I could call if I had questions or required medical assistance. I had follow-up visits with the doctor regularly every three to six months, when the doctor would perform a series of tests and checks, review the results and give me with medications for the time until the next review.

Did you experience any side effects during the trial?
I experienced some of the side effects the doctor and study coordinator had mentioned at the start, but was okay once I got used to the medication. The entire trial process of just over three years was smooth and I would say it was effective for me as I did not experience a second stroke.

What are your afterthoughts to participating in a clinical trial?
I feel I made the right decision. There's nothing to be fearful of in participating in a clinical research trial, as long as it is with a credible organisation. Most importantly, there must be a level of trust between the research volunteers and their doctor. In fact, I am open to participating in future similar trials, if given the opportunity.