

## Does joining a clinical trial make you a guinea pig?

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Clinical trials are carefully designed and monitored for research studies to test drugs, devices or procedures to find out if they are safe and effective before they can be approved for marketing and general public use.

Without a clinical trial, no new medicine or therapy can be approved for use and launched in the market. However, joining a clinical trial does not make one a guinea pig.

Each clinical trial uses specific criteria to determine if volunteers are eligible to participate. These criteria include specific factors, such as age, type of disease, medical history and current health. Depending on the study, participants may be healthy individuals or those with the particular illness being studied. Well-defined inclusion and exclusion criteria are put in place for every clinical trial to ensure that only eligible participants are chosen for the study.

Also, the participants in all phases of a clinical trial receive free medical consultation and medical care. Indian Good Clinical Practices Guidelines clearly state that payments should not be so large or the medical services so extensive so as to act as an inducement for a patient to take part in a study against their better judgement. All payments, reimbursement and medical services are approved by the Institutional Ethics Committee.

The goal of clinical research is to bring superior and life-saving medicines, new devices and medical technologies to patients in need. Safety of the study participants is the most critical component of clinical trials, and that is why there are laws, regulations and processes in place to protect trial volunteers at every step. Nations around the world establish and enforce rules for the ethical conduct of clinical research which ensures that patient safety is made a priority.

Patient safety is of utmost importance in any clinical trial. Clinical study protocols are developed to ensure that risks to study participants are minimized. These protocols are carefully reviewed by an Institutional Ethics Committee as well as country regulatory authority (Drugs Controller General of India) before a clinical trial can start.

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