



MY MARVELLOUS GUIDE TO CLINICAL TRIALS



Help us make Heart Failure clearer for everyone

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WHAT IS A CLINICAL TRIAL?

A clinical trial is a medical research study designed to evaluate the safety and effectiveness of a specific treatment. Trials help doctors and nurses to understand how to treat or prevent a particular condition. They can lead to the development of new or refined treatment pathways in the future.

Every childhood vaccination, clinical procedure and medical intervention in existence today has been through a clinical trials process to ensure that they are fit for purpose and safe. Generations of the human population have benefitted from the clinical trials process. A recent example of this is the COVID-19 vaccine testing and rollout.

TREATMENTS TESTED DURING A CLINICAL TRIAL COVER A WIDE RANGE OF HEALTHCARE APPROACHES INCLUDING:



NEW MEDICINES OR VACCINES



PHYSICAL INTERVENTIONS, PROCEDURES OR DEVICES



PSYCHOLOGICAL THERAPIES



OR EVEN RETESTING A CURRENT DRUG FOR USE IN A DIFFERENT COMBINATION OR IN AN ALTERNATIVE WAY

Some "observational" studies simply monitor a person's symptoms and wellbeing without administering any form of treatment. Other trials involve the use of a placebo, a dummy or inactive treatment, to compare with the new treatment undergoing testing. People receiving the placebo are usually unaware that this is the form of treatment they are taking. The use of a placebo or dummy is necessary to ensure that there is no rigging or bias in the study and that any effect seen is genuinely due to the treatment given.

Typically, trial participants consist of people living with the relevant condition. However, some trials also involve people in good health from the general public or a combination of both.

Researchers do not benefit financially from conducting medical research. However, for every patient who takes part in a trial, funds are given to the NHS. Payments to the NHS range from £1,000-£25,000 per participant but are typically around £6,000. Taking part in a clinical trial could benefit your local NHS hospital and the services they are able to provide. Some trials will offer to pay participants depending on what is involved and how much time it will take. Other trials may only reimburse participants for their travel expenses.



USEFUL LINKS PROVIDING FURTHER GENERAL INFORMATION ON CLINICAL TRIALS:



NHS

<https://www.nhs.uk/conditions/clinical-trials/>



**NIHR (National Institute for Health Research)
Clinical Research Network, North West London**

https://www.chelwest.nhs.uk/your-visit/patient-leaflets/links/copy_of_UnderstandingClinicalTrialsNorthWestLondonBooklet20200217.pdf



UK Clinical Research Collaboration

https://www.ukcrc.org/wp-content/uploads/2014/03/iCT_Booklet.pdf

HOW DO I TAKE PART IN A CLINICAL TRIAL?

For some conditions or illnesses, it is commonplace to be approached by your Consultant or Nurse to see if you would like to take part in a clinical trial, but this is not always the case.

If you would like to be proactive and actively seek out a clinical trial for your condition, you can ask your healthcare professional or a patient organisation if they are aware of any clinical trials that may be suitable for you.

There are also several websites where you can search for information on clinical trials and register your interest in specific studies you are eligible for and may wish to contribute to. Though it is important to remember that there may not be any trials available that are a good fit for you at the present time, that may change in the future.



To find a UK based heart failure trial near you, please register with our platform, CardioTrials.

<https://cardiotrials.org/>

WHAT IS CARDIOTRIALS?



We believe everyone should have the opportunity to participate in medical research that best suits their interests, needs and requirements.

In simplest terms, CardioTrials is like a dating site. It matches:

- 1) heart failure patients looking to participate in clinical trials
- 2) researchers looking to recruit participants to take part in their heart failure research studies

Patients sign up to CardioTrials and create a profile with their heart failure related medical information.

The lead researcher of a trial, the Chief Investigator (CI), onboards their trial onto CardioTrials. They indicate 'inclusion criteria' and 'exclusion criteria' – e.g. medical conditions required or which rule out participation in the trial.

If a patient's profile matches the equivalent trial 'profile', the patient is alerted that there is a trial which may be of interest to them. They can then choose to register their interest in the trial by viewing more details about what is involved. Or they can choose to do nothing.

Initial introduction of the patient to the researcher is anonymous. When the patient registers their interest, some relevant medical details are presented to the researcher. This enables a high-level assessment to see if the patient may be a good fit for the study.

The next stage of introduction is only done with express permission of the patient. Further detailed medical information, including medical number, which then makes the patient identifiable, may be requested from the patient. This allows for a more detailed assessment to be carried out.

If a patient is accepted onto a trial, all further communication is conducted outside of CardioTrials. Patients are informed of the decision via email within defined and agreed timescales.

100% control is in the hands of the patient throughout the entire application process. The patient has the right to change their mind and withdraw their interest in a trial at any time on CardioTrials. Patients can delete their account at any time and have the right to be forgotten.

It is often not possible for researchers to search a database of patients to find potential participants for their trial on CardioTrials. CardioTrials adheres to all ethics and GDPR considerations. With CardioTrials a patient's data is safe and secure.

Signing up is simple and free. Visit our platform to register today!
<https://cardiotrials.org/>

Healthcare professionals can also use CardioTrials to give them visibility of available heart failure trials within a 50-mile radius of their entered work location so that they may present and discuss this information with their heart failure patients.



WHY IS CARDIOTRIALS IMPORTANT?

In a poll conducted in July 2019, 87% of patients with heart failure had never been approached to participate in a clinical trial. This is a lost opportunity for both patients and researchers to improve their care.

It is imperative that clinical trials engage with patients who are representative of the clinical problems that they are designed to investigate. Sufficient numbers of people must be enrolled to ensure the studies have enough power to demonstrate important treatment effects that will improve patient care. Unfortunately, some trials cannot recruit adequate numbers to give the outcomes enough statistical validity and potentially life-changing treatments are never proved. Rapid recruitment gets quick answers and enables more problems to be addressed. Patients and trialists (from many clinical disciplines) are coming together to identify key questions that affect their daily lives and the advice and treatment on offer.

CardioTrials has been developed with assistance from Professors John Cleland and Mark Petrie from the University of Glasgow and supported with funding from Vifor Pharma.



Scan this QR code to listen to Professor Mark Petrie and our CEO Nick talk about clinical trials and CardioTrials.



USEFUL LINKS

To find out more from people who have taken part in clinical trials for many different conditions, please visit this link to hear about their experiences:

<https://www.healthtalk.org/peoples-experiences/medical-research/clinical-trials/topics>

There are many new terms, acronyms and jargon to get to grips with when learning about clinical trials.

This link has a list of useful explanations which are helpful as a starting point:

<https://powerfulpatients.org/2019/12/02/understanding-clinical-trials-a-jargon-buster-guide/>

These two links are more comprehensive but aimed more at people with a clinical background.

NIHR (National Institute for Health Research)

<https://www.nihr.ac.uk/documents/commonly-used-research-abbreviations-and-terms/12227>

University Hospitals Bristol NHS Foundation Trust

http://www.uhbristol.nhs.uk/media/2117444/commonly_used_research_abbreviations_and_terms.pdf



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