

## CLINICAL TRIALS

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Health

Health

## Northwick Park drug trial disaster - could it happen again?

By Philippa Roxby

Health reporter, BBC News

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**Before any new medicine can be given to patients, detailed information about how it works and how safe it is must be collected.**

Clinical trials are the key to getting that data - and without volunteers to take part in the trials, there would be no new treatments for serious diseases such as cancer, multiple sclerosis and arthritis.

But one disastrous drug trial at a London hospital in 2006 threatened to derail that system.

In what became known as the Elephant Man trial, **six healthy young men were treated for organ failure** after experiencing a serious reaction within hours of taking the drug TGN1412 in a clinical trial.

After they were all admitted to intensive care, two became critically ill, the worst affected lost his fingers and toes, and all the men were subsequently told they would be likely to develop cancers or auto-immune diseases as a result of their exposure to the drug.

In follow-up interviews, **the men described feeling like their brains were "on fire" and their "eyeballs were going to pop out"**.

Experts queued up to say the outcome of the trial had been unprecedented and exceptional, but could it happen again?

Prof David Webb, professor of therapeutics and clinical pharmacology at the University of Edinburgh and vice president of the British Pharmacological Society, says it is "much less likely to happen again".

He says things have changed for the better since 2006, following a number of recommendations made in the Duff Report, written in response to the trial.

"The MHRA [Medicines and Health products Regulatory Agency] now ensures committees look at pre-clinical data, to decide whether the first dose given to humans is the right dose and has rules for stopping if things don't go as expected."

This is particularly important when trials involve drugs that affect the immune system, he says.

But is it possible to eliminate the risks entirely?

"You can mitigate against the risks, but nothing is 100% certain. We can never be sure," Prof Webb says.

The trial, which was privately run at a research facility at Northwick Park Hospital in north London, involved the first testing of a new drug on humans. This is the initial phase in assessing the safety of a drug before moving onto larger-scales studies in patients themselves.

The report said **Parexel**, the company managing the trial, had been unclear about a safe dose to start testing on humans and it should have tested the drug on one person at a time.

The MHRA, which regulates clinical trials and medicines in the UK, and which was criticised at the time for giving the green light to the TGN1412 trial, says the conduct on these phase-one trials "has moved on significantly".

"Additional provisions and guidance has been put in place for certain novel products to provide as much assurance on safety as possible," the agency says.

It adds that it has simplified and streamlined the regulation of clinical trials and collaborated with other bodies and experts to collect as much information as possible on risk factors before a trial is authorised.

Phase-one trials, when drugs are tested on humans for the first time, only happen after extensive testing on tissue samples and animals in the lab.

Getting this stage right before moving onto research in humans is crucial.

Dr Catherine Elliott, director of clinical research interests at the Medical Research Council, which funds clinical trials in the UK and globally, says there is a move to refine the models used at the pre-clinical stage.



"Animal models are the mainstay, but we are trying to develop other models too to have more tailored disease models."

She says researchers are making use of brain imaging to understand the mechanisms of illness in humans and using IT to predict the effects of new drugs.

Testing on animals, which has its own controversies, can get scientists so far - but someone always has to be the first person to test a new medicine.

The volunteers for phase-one clinical tests always have to be healthy young men because of the risk to a woman's eggs or foetus.

Prof Webb says we are indebted to the 50 to 100 people in the UK each year who step forward to begin the testing of every new drug.

"There are so many effective medicines for cancer, heart disease et cetera - and they all come from volunteers who have taken part in small, early studies."

He believes that everyone who wants to should be able to register themselves available for clinical research through their GP.

"I would argue that everyone should be a volunteer. We'd get the payback eventually because by the time we're in our 60s and 70s most of us will end up on medicines."

Although volunteers are compensated for their time and inconvenience during the trial, they are not paid for taking part - and Dr Elliott says this is the correct approach.

"There shouldn't be an incentive to do something they wouldn't otherwise do. It shouldn't be related to risk. People have to be able to give free consent."

Despite all this, there appears to have been no reduction in interest in participating in early-stage trials since Northwick Park.

The MHRA says the number of UK clinical trial authorisation applications has been fairly stable at 900-1,000 per year since May 2004.

Prof Webb says he has always found it relatively easy to find volunteers for the "first in man" trials he oversees at his approved research centre in Edinburgh.

The MHRA is in no doubt about the safety of drug trials, seven years on from Northwick Park.

A representative said: "Clinical trials in the UK have an excellent safety record and they play a vital role in the development of new medicines, providing evidence so that clinicians can make informed prescribing decisions.

"Safety problems associated with clinical trials are rare and the risk of a repeat of the incident in 2006 concerning the TGN1412 drug is extremely low."

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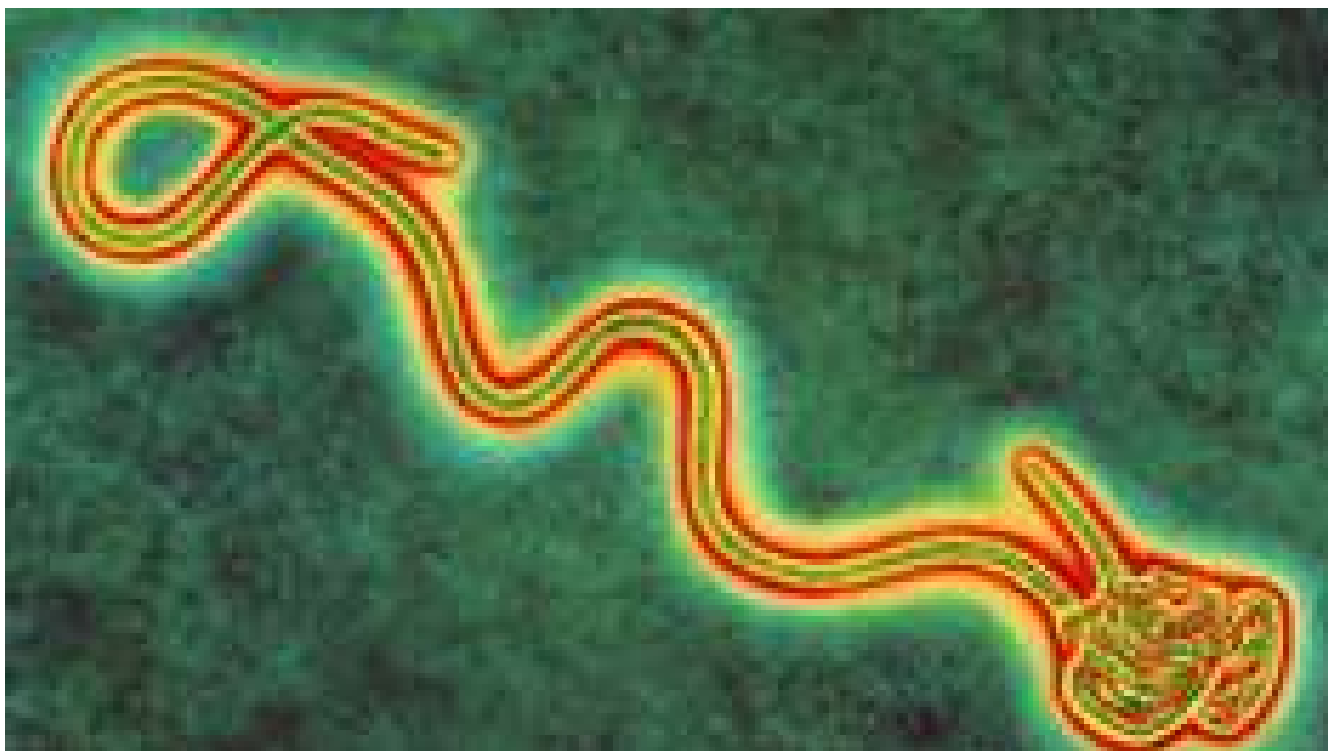
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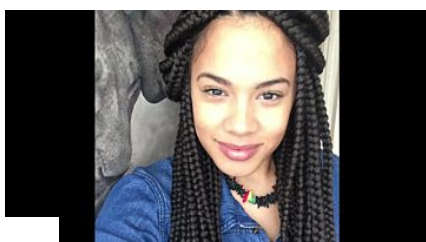
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