

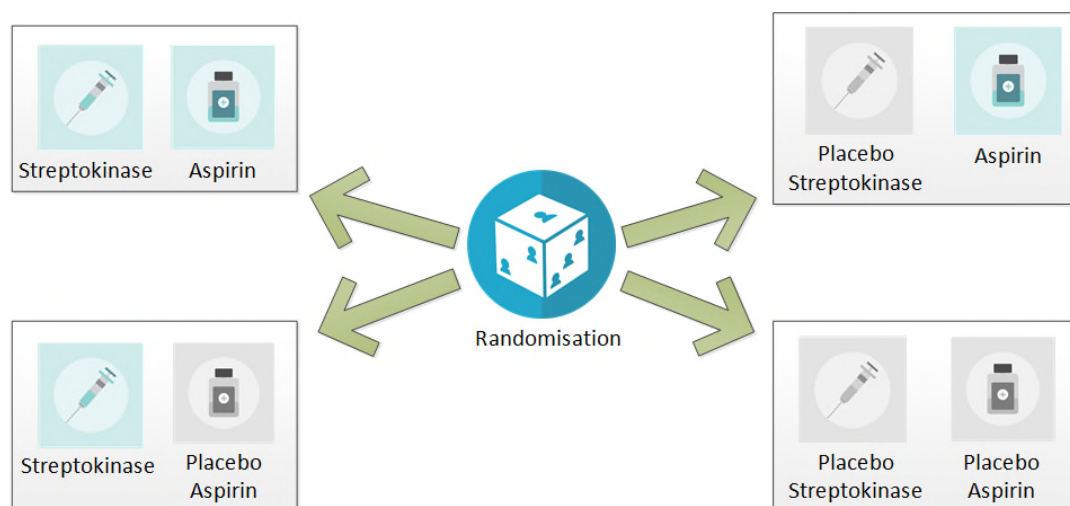
ISIS-2 Information for Participants

Introduction to ISIS-2

Recruitment for the ISIS-2 main trial took place in hospitals between March 1985 and December 1987, with 6,213 patients recruited in the UK (and 10,974 patients in 15 other countries). Patients entering the trial had had an acute heart attack and were randomised within 24 hours of the start of chest pain. Patients were mostly between 60-69 years old. They received either intravenous streptokinase administered over an hour (used to dissolve blood clots in blocked arteries) or matching placebo, plus oral aspirin (a blood thinner) taken for a month or matching placebo.

Treatment allocation

Participants were randomly allocated the different treatments as shown:



ISIS-2 data collection and processing

Recruitment into the trial stopped in December 1987 after which the ISIS-2 study team continued to collect medical information from electronic health records held by UK Central Registries such as the ONS (Office for National Statistics). This was done until 1997 to identify how many people had died.

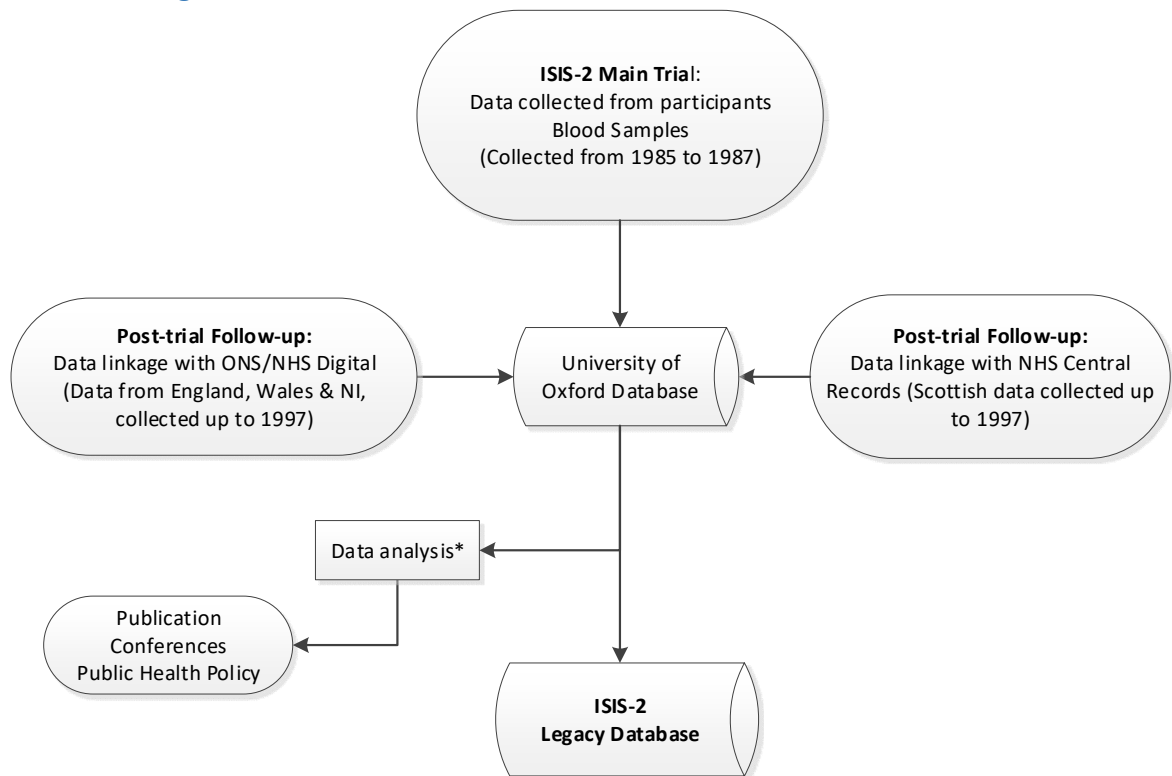
The trial found that patients taking streptokinase and/or aspirin were more likely to survive than those taking the placebo. These results transformed clinical practice worldwide and are still relevant today. Initial results were published in 1988, with follow-up results published in 1998, which showed that the benefits lasted for at least 10 years.

This unique dataset and the research which has used it significantly contributed to the evidence and knowledge available which led to changes in treatment, care and policies which are of ongoing benefit to patients and health care systems.

The researchers at NDPH intend to keep the data used for the original ISIS-2 analyses for the following reasons:

1. To be able to preserve the dataset which produced these important findings and to have it available to recreate the published trial results if required.
2. To allow the option for future research using the original dataset, e.g. looking at different research questions to the results already published (in-line with the original protocol), and to be able to keep the possibility to do long-term data linkage e.g. to see what happened to the patients for the whole course of their life. In such a situation appropriate applications (e.g. to an ethics committee, the Confidentiality Advisory Group, & NHS Digital) justifying the analyses would be made and approved before any new work could be done.

Data Flow Diagram



*Data analysis completed in 1998, no work is ongoing.

Why is ISIS-2 important?

While ISIS-2 was done many years ago, the findings are still relevant globally today. The finding of using drugs - such as streptokinase - to dissolve blood clots in patients who had had an acute heart attack has led on to other therapies in high income countries (such as non-surgical procedures to treat blockages in coronary arteries). However, treatments similar to streptokinase remain by far the most commonly used emergency treatment for acute heart attack worldwide. This is typically because in lower income countries there are not facilities to provide more complex and costly treatments, or because the time from symptom onset to hospital admission is too long for other treatments to be used. This can also be an issue in high-income countries – including the USA – where healthcare transit times are long.

ISIS-2 is one of the few trials demonstrating the benefits and the safety of treatment with streptokinase. It is also the only trial that has demonstrated the benefit of aspirin in the setting of acute heart attack.

Privacy Notice

A Privacy Notice for participants has been provided on our website

<https://www.ctsu.ox.ac.uk/research/international-study-of-infarct-survival-isis> to explain how we use patient data.