

Children with heart disease are being let down by lack of clinical trials, study finds

November 22 2017

Less than one per cent of UK children born with congenital heart disease are enrolled in clinical trials looking to improve treatments, research funded by the British Heart Foundation and led by the University of Birmingham and Birmingham Children's Hospital has found.

The study, published in the *European Journal of Cardio-Thoracic Surgery* today, is the first systematic review of its kind into clinical trials in [children's heart](#) surgery.

The researchers analysed all 333 clinical trials published world-wide between 1st January 2000 and 31st August 2016 on surgery for [congenital heart disease](#) - heart conditions that develop in the womb and the most common type of birth defect. They found only 10 clinical trials (three per cent) were conducted in the UK in this time, none of which were phase III trials - large, influential trials needed to change treatments or guidelines.

The researchers also found that only 431 out of the estimated 65,000 (less than one per cent) children who underwent [heart surgery](#) in the UK in this timeframe were enrolled in a clinical trial. In comparison, 70 per cent of children suffering from cancer are enrolled in phase III clinical trials.

Although recent advances mean most children diagnosed with a [congenital heart defect](#) grow up to become adults, many face the prospect of multiple surgical operations, and sadly around 400 children

each year still die before they reach school age.

Poor recruitment was not able to explain the lack of clinical trials, with over 87 per cent of trials able to recruit sufficient children. However, there are many different types of congenital heart diseases and it can be difficult for single hospitals to see enough of a particular type of the disease to carry out a meaningful trial.

Researchers suggest that one solution to this issue would be to establish a congenital heart disease research network which would allow researchers in all centres in the UK to collaborate and carry out research into the rarest types of congenital heart disease.

Lead author Mr Nigel Drury, of the Institute of Cardiovascular Sciences at the University of Birmingham and consultant in paediatric cardiac surgery at Birmingham Children's Hospital, said: "The surgery available for children with heart problems has improved dramatically over the past twenty years.

"However, by not carrying out large-scale, cutting-edge clinical trials to continually improve surgeries, we're letting down the thousands of children born in the UK each year with heart problems."

As a congenital heart disease community, we have a responsibility to provide scientific leadership and work together to conduct well designed, rigorously conducted, multi-centre clinical [trials](#) to improve the outcomes of surgery for our patients and their families." The startling research is being highlighted as part of the BHF's Christmas Appeal, which aims to raise £750,000 for life saving research towards congenital heart disease, which affects around 4,000 UK children each year.

Professor Sir Nilesh Samani, Medical Director at the British Heart Foundation, said: "For many children with congenital heart disease, the

only treatment available is [surgery](#). It can be a difficult choice for parents to agree to their child participating in research. However, the only way we can improve the range and quality of treatments for these children is through [clinical trials](#).

"This study shows that we can and should do better if we are to improve the treatment and outcomes of children with congenital heart [disease](#)."

More information: Drury et al (2017). 'Randomised controlled trials in children's heart surgery in the 21st century: a systematic review'. *European Journal of Cardio-Thoracic Surgery*. [DOI: 10.1093/ejcts/ezx388](#)

Provided by University of Birmingham

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