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Clinical trial to test success of Cystic Fibrosis lung infection treatment

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Experts from Bristol and Nottingham are leading a major new national study to investigate whether intravenous antibiotics are effective in killing a common germ that causes dangerous complications in cystic fibrosis (CF) patients.

The team is hoping to find out if the treatment is more effective than traditional therapies in tackling Pseudomonas aeruginosa, which causes a chronic destructive lung infection in CF patients and which cannot be eradicated unless it is caught in the early stages.

Dr Simon Langton Hewer, from University Hospitals Bristol NHS Foundation Trust, who is chief investigator of the study, said: "It's very exciting to have a clinical trial available to CF patients around the whole of the UK. This is the first CF trial for many years to be run in the UK and will answer one of the important questions affecting CF patients."

Professor Alan Smyth in The University of Nottingham's School of Clinical Sciences, a co-investigator in the TORPEDO clinical trial, said: "Children and adults with CF are now receiving intravenous antibiotics for Pseudomonas more and more often, with no good evidence that this is more effective. We want to see if intravenous antibiotics do work better than traditional oral treatment because oral treatment is easier to give at home and does not require a hospital admission."

Pseudomonas aeruginosa is a bacterium that lives in the environment, lurking in places such as sink drains. Most CF patients have chronic lung

infection with the germ by their late teens. Oral and nebulised (inhaled) antibiotics have mainly been used to eradicate Pseudomonas, but are often only effective if the infection is caught in time.

Intravenous antibiotics are being used more often to treat the infection, however, there is no current clear scientific evidence that intravenous treatment is better than oral treatments. Intravenous treatment means that patients with CF need to spend up to two weeks in hospital in addition to the medication they may previously have been prescribed.

The new trial is funded with £1.5 million from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme and sponsored by University Hospitals Bristol NHS Foundation Trust. So far, 41 CF centres and clinics around the UK have signed up to the trial — coordinated from the Medicines for Children Research Network (MCRN) Clinical Trials Unit in Liverpool — with the aim of recruiting 280 volunteer CF patients.

Adele Whitford from Severn Beach near Bristol, whose daughter has cystic fibrosis, said: "We decided to take part in the trial because we want to help improve the care for cystic fibrosis patients. As a nurse, part of my job is to provide best evidence practice and without research being carried out you haven't got that evidence."

Zoë and Steve Elliott, of Mapperley Park, Nottingham, have two-year-old twins Alexander and Isobel who were both diagnosed with CF shortly after they were born. They say they didn't hesitate in getting the twins involved with the trial and hope the research will give parents of children with CF firm evidence of whether IV antibiotics really do offer the best treatment option.

Zoë said: "When we were invited on to the trial I was initially really surprised that this research hadn't already been done because in our

experience IV antibiotics are generally perceived among parents of children with CF to be the best way of eradicating the infection. As a mum, if it's a toss-up between being at home with a nebuliser for three months or having your child in hospital having invasive treatment for two weeks I know what my gut instinct tells me — it's home every time. But it would be reassuring to have some firm evidence to allow us to make a more informed choice and that's why this research is long overdue."

Matthew Reed, Chief Executive of the Cystic Fibrosis Trust said: "Pseudomonas infection is a leading cause of lung damage in people with CF so it is important to find the most effective way to eradicate this bug and therefore help people with CF to live longer. We commend the team at Nottingham and Bristol for their initiative on this study and hope that suitable people with CF throughout the UK will agree to take part in this important piece of research. It is great to see so many UK CF centres (large and small) involved and we would encourage centres not yet taking part to sign up for the trial."

Patients with a new *Pseudomonas aeruginosa* infection which has been identified through a routine sample from the lungs are being invited on to the study and are given (at random) either two weeks of intravenous antibiotics and three months of nebulised antibiotics or three months of combined oral and nebulised treatment. They will then be followed up for a further 15 months through routine clinic visits to assess whether the germ has been eradicated and stays away for at least a year.

If the trial finds that intravenous antibiotics are more successful in treating the infection, this will form the basis of national guidelines on standard medical practice and mean that patients have access to a more effective treatment.

If intravenous treatment doesn't work as well as traditional methods, it

could spare patients the inconvenience of hospitalisation, the trauma of having an intravenous cannula inserted — a particular problem for many children suffering from CF — and the upset of missing school or work for two weeks.

More information: The trial is open to adults and children with CF (excluding babies under one month old) and further information about the trial and how to participate can be found at www.torpedo-cf.org.uk/index.html

Provided by University of Nottingham