

Cord Reinfusion in Diabetes (CORD) Pilot Study – Questions & Answers

Q. What is the Cord blood Reinfusion in Diabetes (CORD) Pilot Study?

A. The CORD study is a world first study that will investigate the potential of using a child's own cord blood, collected from the umbilical cord and placenta at birth, to prevent or delay the onset of type 1 diabetes in children at high-risk of developing the condition.

Q. What is the study hypothesis?

A. Type 1 diabetes results from an autoimmune process which leads to the destruction of insulin-producing cells in the pancreas. The study is looking at whether regulatory T cells, found in cord blood, can prevent or delay this immune destruction and protect children from developing type 1 diabetes.

Q. Why is cord blood being used?

A. Cord blood is rich in important and unique immune cells, known as regulatory T cells, as well as stem cells. This study will investigate whether these regulatory T cells can prevent or delay the destructive immune response that is known to occur in the pancreas with type 1 diabetes and protect the child from developing the condition.

Q. Why is this pilot study important?

A. This study is important because Australia has one of the highest rates for type 1 diabetes in the world, with the number of people living with type 1 diabetes increasing 3% annually. There is currently no cure or successful prevention measure for type 1 diabetes which requires lifelong management and can lead to a number of health complications. This study will allow the researchers to assess the potential of cord blood to prevent the onset of type 1 diabetes.

Q. Where is this pilot study taking place?

A. The study is being led by Professor Maria Craig at The Children's Hospital at Westmead in New South Wales. The study is open to participants located anywhere in Australia.

Q. Who is participating in the study?

A. Children aged 1 and 15 years who have their own cord blood stored privately, and who have a close relative with type 1 diabetes, may be eligible to participate in the study.

Q. What will the study involve?

A. There are two phases in the pilot study:

1. Screening Phase: Eligible children will have blood taken every 6 to 12 months to detect the presence of early markers of type 1 diabetes, known as antibodies
2. Treatment and Follow-up Phase: Children who test positive for 2 or more of antibodies during the Screening Phase will undergo tests and assessments to see if they can receive treatment with their own cord blood. These children will then be followed for 3 years.

Q. Is this study approved?

A. This project has been approved by the Sydney Children's Hospitals Network Human Research Ethics Committee. If you have any concerns about the conduct of this study, please do not hesitate to contact the Secretary of the Ethics Committee on (02) 9845 1253 and quote reference number **11/SCHN/211**.

Q. How can I find out more?

A. For further information about the study, please contact the CORD Study Coordinator/Nurse at The Children's Hospital at Westmead via:

Email: SCHN-CHW-CORD@health.nsw.gov.au

Phone: (02) 9845 3512

For further information about cord blood storage, please contact Cell Care on 1800 071 075 or visit www.cellcareaustralia.com.