



Dear Parent

Welcome to the PROTECT study!

We are Seema and Sarah, fellow mums who have been through pregnancy with Type 2 diabetes and are now working as advisors with the PROTECT research team. We would like to invite you on board as an essential member of our PROTECT community of pregnant women with Type 2 diabetes. Together, with doctors and researchers, we are working towards improving the lives of mums and their babies.

The PROTECT study aims to find out if continuous glucose monitoring (CGM) is more effective than finger-prick testing for pregnant mums with Type 2 diabetes. If we can show that CGM is better for managing glucose levels, the NHS will be able to offer this technology to pregnant mums with Type 2 diabetes in the future. By taking part in this study, you would be playing a crucial role in getting us the information to help make that happen.

As Type 2 mums, we understand the challenges of managing glucose levels during pregnancy, and also how important this is for a healthy outcome for you and your baby. We are excited about the potential for this study to make life better for countless mothers and babies.

We wish you all the best with your pregnancy.

Best regards

Seema Hussain



Sarah Dunkley



PARENT INFORMATION SUMMARY

This is a summary of PROTECT, a study aiming to improve the care of babies being born to mothers with Type 2 diabetes. Please read it carefully and ask us if anything is unclear.

Why am I being given this information? Your antenatal clinic is one of several across the country taking part in the PROTECT study to find out the best way for mothers with Type 2 diabetes to monitor their glucose levels during pregnancy. This involves pregnant mothers being assigned to using either finger-prick or continuous glucose monitoring.

What happens at the moment? We ask all pregnant mothers with Type 2 diabetes to monitor their glucose levels. This is to make sure that their babies don't get too much extra glucose and become too big, as this can cause problems for mum and baby, during and after birth. Most clinics use finger-prick glucose monitoring, although a few have started to offer some women continuous glucose monitoring.

Why is this study needed? We do not know which type of glucose monitoring helps pregnant mothers to keep their glucose **in target**. We do not know if it is **better for baby** if mum uses finger-prick monitoring to see their glucose level a few times a day, or whether it is better if mum wears a continuous glucose monitor that provides glucose levels all the time.

Finger-prick glucose monitoring involves the mum pricking her finger with a small needle to get a drop of blood at least four times a day (on waking and after each meal). The blood is put on a small strip that is put into a reading device, which gives a glucose level. This is recorded in a diary, and the information is used by mum and the clinical team to decide what treatment is needed to keep the glucose levels in target. Mum needs to carry the kit to monitor her finger-prick glucose with her all the time.



Continuous Glucose Monitoring (CGM) is a newer way of looking at glucose levels. It involves wearing a small sticky sensor (about the size of a £1 coin) on the arm for two weeks at a time. This sensor connects with mum's smartphone via an App. It measures the glucose every minute, day and night, and sends the information by Bluetooth to mum's phone. This is shared with the clinical team to decide what treatment is needed to keep the glucose levels in target. Mum and the clinical team can see what is happening with the glucose levels for the whole 24-hour day, all through pregnancy.

After two weeks the sensor can be peeled off and a new one is put on. Mum needs to keep her phone charged and carry it with her all the time.

How do we find out which is better? The most reliable way is by fairly allocating pregnant women to use either finger-prick or continuous glucose monitoring. A computer does this for us without influence, so that half will use one approach and half will use the other. This gives women an equal, fair chance of receiving either form of monitoring. We will need to compare information from about 422 women and their babies to find out which option is better.

Other information There are no additional risks to you or your baby from taking part in this study because both glucose monitoring options are already widely used across the NHS. We will keep all details about you and your baby private. The only people allowed to look at you and your baby's data are the team involved in the study and the authorities responsible for checking that it is carried out correctly.

Thank you for reading this. If you are interested in taking part in the study, please speak with your clinic team. We wish you all the best with your pregnancy.