TCS/21/09 - Proof-of-concept for using a novel formulation of metformin (Metformin Delayed Release) to optimise treatment of gestational diabetes

We address the unmet clinical need for an effective, well-tolerated, and safe drug therapy for women with gestational diabetes, the most common pregnancy complication. Metformin is used as first-line drug therapy to control blood sugar levels and has significant advantages for women, including that it is a tablet and it helps limit pregnancy weight gain. However, metformin has poorly tolerated side-effects including nausea and diarrhoea. It also freely crosses the placenta, and emerging evidence suggests potential for adverse child health outcomes including obesity. Our proposed solution is a new “delayed-release” metformin tablet which we hypothesise will substantially reduce levels of metformin in the mother’s blood. This will reduce transfer of metformin across the placenta compared to standard metformin tablets, minimising the potential for adverse effects of metformin exposure for the child. We also believe this metformin preparation will have fewer side effects, which will encourage women to take their treatment regularly, thus improving their blood sugar control and avoiding the need for insulin injections. We request funding to demonstrate lower fetal metformin exposure in women treated with metformin delayed-release vs. standard metformin tablets. In addition, we will find out if metformin delayed-release is a feasible and acceptable drug for women with gestational diabetes. We will also seek views from pregnant women to inform and develop a larger clinical trial. Our findings will support an application for a clinical trial using metformin delayed-release as a treatment to optimise management of gestational diabetes with fewest side-effects for mother and baby.