

The efficacy of sildenafil therapy in dismal prognosis early-onset intrauterine growth restriction: the STRIDER RCT

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Plain language summary

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Plain language summary

Babies that are very small in the womb are at greater risk of a poor outcome to the pregnancy such as stillbirth and learning difficulties in surviving children. Usually, a baby grows small because the placenta, which feeds the baby, is poorly formed.

The study wanted to know whether using a medication, which improves the blood supply to the placenta, will give the baby more nutrition and allow better growth. This would allow doctors to keep the baby inside the womb for longer. The study used a medication called sildenafil to improve the blood supply. To be sure if it worked, the study wanted to compare this drug against an identical looking blank tablet (placebo) so women and their healthcare professionals would not know what medication was being given.

Women with very small babies and who were pregnant between 22 weeks and 0 days to 29 weeks and 6 days were asked to take part in the study. Treatment was three times a day and continued until delivery or 31 weeks and 6 days. A total of 135 women agreed to take part in the study. Seventy were given sildenafil and 65 were given placebo. A computer decided which medication would be given to which women with a 50 : 50 chance of each. Women were kept in the study until discharge of their baby from hospital. Surviving babies were seen with their mothers at 2 years of age to test for brain injury and problems with thinking, speech and language, or movement (neurodevelopment).

The study showed no benefit of sildenafil when compared to placebo in helping the baby grow or in preventing early delivery.

In surviving babies there was no benefit for neurodevelopment 2 years after treatment with sildenafil.

The findings of our study mean that sildenafil should not be used for the treatment of small babies.

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