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LETTERS

STOPPING OF VIAGRA TRIAL

Protect pregnant women by including them in clinical research

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The decision to stop the STRIDER trial with sildenafil (better known as Viagra) to improve uteroplacental blood flow, fetal growth, and infant outcomes for fetuses with severe growth restriction was disappointing for all involved.¹ International media extensively reported on this trial, triggering debates in academic journals and (social) media.²⁻⁴ But one aspect remains neglected: although results of the trial were undesirable, conducting clinical research in pregnant women is crucial. The importance of clinical trials with pregnant women has been argued and defended for decades, and these efforts should not be abandoned.^{5,6}

The response to the STRIDER trial shows the paradox in research with pregnant women—wanting to protect women and fetuses from harm, physicians, midwives, and researchers are reluctant to include them in clinical research, but it is the only way to increase the evidence base about safety and efficacy of drugs in pregnancy. Moreover, we must consider the risks of not conducting research in pregnant women: prescription of treatments for pregnant women without systematic assessment first. Sildenafil has been prescribed by doctors around the world for women with pregnancies with severely growth restricted fetuses.^{7,8} It is only because of this study that the potential adverse outcomes are now flagged.

Clinical research with pregnant women should not be prevented but encouraged. All stakeholders must encourage carefully designed and executed research, which observes normative considerations such as acceptable levels of risk and the optimal

use of safety and efficacy data from the non-pregnant population (fig 1).⁹ Ultimately, we need research like this to increase the evidence base and improve maternal and fetal health.

Competing interests: None declared.

Full response at: <https://www.bmj.com/content/362/bmj.k3247/rr>.

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Figure

Fig 1 Infographic developed by University Medical Center Utrecht, ZonMw, and Sticky Visuals

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