

PATHWAYS clinical trial paused following new MHRA advice

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MHRA has raised new concerns around the PATHWAYS trial looking into the prescription of puberty blockers among young people with gender incongruence.

The preliminary work in establishing the PATHWAYS clinical trial into the prescription of puberty blockers for children and young people with gender incongruence has been paused, following new concerns raised by the medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA).

Discussions between MHRA and the trial sponsor, King's College London, will begin next week to address the new concerns. In the meantime, the trial will not start to recruit until issues raised by MHRA have been resolved between the regulator and the trial clinicians.

A Department of Health and Social Care spokesperson said:

We have always been clear about the red lines regarding this trial - ensuring the safety and wellbeing of the children and young people involved and always being led by the clinical evidence.

MHRA has now raised new concerns - directly related to the wellbeing of children and young people - and scientific dialogue will now follow with the trial sponsor.

As the evidence is now being interrogated by clinicians, preparations for the trial have been paused while MHRA and clinical leaders work through these concerns.

This trial will only be allowed to go ahead if the expert scientific and clinical evidence and advice conclude it is both safe and necessary.

The safety and wellbeing of children and young people have always been the driving consideration in every decision we have made regarding this trial and always will be.

<https://www.gov.uk/government/news/pathways-clinical-trial-paused-following-new-mhra-advice>