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Protocol opinion

What the expert committee said on Stamina's methods

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The report of the original expert committee tasked with looking at Stamina's clinical protocol includes the following opinions:

The protocol contains no method for screening for pathogens such as prions or viruses, even though the culture medium used could contain them.

The method it describes for producing mesenchymal stem cells, say the experts, would generate a mixture of different cell types that could include blood-cell precursors and bone fragments.

The method it describes for checking the biological identity of the cells uses inappropriate cell-surface markers and no functional assay. And the protocol does not include a method for making mesenchymal stem cells differentiate into neural cells, the rationale Stamina provided, along with the protocol, in support of the clinical value of the method in three disorders it proposed that the clinical trials address.

Even if the Stamina method did generate the desired cells, the experts' report notes, there would be too few of them for the treatments Stamina proposes. The experts also criticized an 'emergency' measure in the protocol that would culture a patient's sample once more just before injection if at the last minute numbers of stem cells appeared sparse. This would mean that treatments across patients in the clinical trial would not be standardized, they say.

The clinical rationales provided by Stamina also contain conceptual errors, the experts say, as it is broadly accepted by the scientific community that the stem cells can differentiate into only bone, fat or cartilage. Moreover, the committee notes that sections of the protocol are copied.