

Call to delay clinical trials for gel stroke treatments

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Clinical trials of new gel treatments for stroke should be delayed until technology used in the tests is improved, according to research led at the University of Strathclyde.

The researchers claim that failure to do so could have "devastating"

effects on the prospects for the treatments being used for [stroke](#) and other conditions.

Stroke currently has a lack of treatments, partly because, so far, stem cell-based therapies cannot be used for chronic stroke.

Effective treatment

Gels have the potential to be an [effective treatment](#) for stroke, owing to their capacity to fill cavities in the brain created by strokes and their ability to interact with glial scars, a type of scar which forms in the area of the cavity and seals it off from the rest of the brain.

Gels could also be effective in payload delivery of drugs and [stem cells](#), owing to unique properties which can be tuned to the requirements of a specific stroke site.

But no [clinical trials](#) have so far been successfully commissioned to explore the potential of regenerative gels for the treatment of [chronic stroke](#). This was partly due to pre-clinical laboratory studies not taking into account the full range of ages and health conditions of stroke patients.

Better understanding

The researchers reviewed more than 90 research papers from the past five years, focusing on five types of gels with potential for use in stroke, and found that this amounted to a "bottleneck" in the development of new therapies. The authors recommend that studies achieve a better understanding of how gels interact with human stroke tissue, as well as of the effects of scaling up gel volume to the size of stroke patients' cavities.

The study has been published in the journal *Trends in Biotechnology*.

Dr. Hilary Carswell, a Reader in the Strathclyde Institute of Pharmacy and Biomedical Sciences, is lead author of the study. She said: "Stroke is a huge unmet clinical need and there is an urgency in the move towards new treatments. There has been success in some pre-clinical trials of gels but our research has identified gaps in knowledge that need to be addressed before clinical trials go ahead. Stroke often has many co-morbidities, such as hypertension, diabetes and obesity but gels proposed for use haven't yet been tested against these conditions. A stroke cavity can be as big as 50 cm³ so pre-[clinical research](#) needs to be scaled up to the size of the human brain. Gels have many benefits but we need to get these things right before they can go to clinical trials and be translated into treatments."

Cautious approach

The authors state: "We urge a delay in commissioning clinical trials to minimize the risks of poor performance at early trial stages. Whilst this is frustrating considering the overall slow progress in development of stroke therapies, the importance of successful gel-based clinical trials cannot be understated. If unsuccessful, premature gel-based clinical trials could have devastating effects on the future of these technologies, both in stroke and in wider regenerative applications.

"Therefore, in order to maximize the future of regenerative [gels](#) and fully realize their potential, there is a requirement to take a cautious approach to ensure their success when they ultimately enter the clinic."

Stroke is one of the leading causes of death and disability globally. In around 85% of cases, stroke is caused by an ischemic event due to a blockage in the blood supply in the brain.

More information: John D. Totten et al, Towards clinical translation of 'second-generation' regenerative stroke therapies: hydrogels as game changers?, *Trends in Biotechnology* (2021). [DOI: 10.1016/j.tibtech.2021.10.009](https://doi.org/10.1016/j.tibtech.2021.10.009)

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