



HEART & STROKE FOUNDATION  
**Canadian Partnership  
for Stroke Recovery**

## **Stroke Recovery and Stem Cells** Frequently-Asked Questions (FAQs)

To get the answers to patients' and families' most-frequently-asked questions about stem cells and stroke recovery, we interviewed three experts.

### **Dr. Dale Corbett**

(<http://www.canadianstroke.ca/en/about-us/our-people/scientific-leadership/>)

Scientific Director and CEO

Heart and Stroke Foundation Canadian Partnership for Stroke Recovery (CPSR)

Professor, Faculty of Medicine, University of Ottawa.

*Dr. Corbett is a neuroscientist and stroke recovery research leader. He has done pre-clinical work on the effectiveness of stem cells in stroke recovery.*

### **Dr. Dar Dowlatshahi**

([www.ohri.ca/profile/ddowlatshahi](http://www.ohri.ca/profile/ddowlatshahi))

Stroke Neurologist and Scientist, The Ottawa Hospital

Scientific Director of the Ottawa Stroke Program

Scientist, University of Ottawa Brain and Mind Institute

*Dr. Dowlatshahi leads a clinical stroke research team. He has conducted clinical trials across the continuum of stroke – from prevention to acute treatment to recovery.*

### **Dr. Duncan Stewart**

([www.ohri.ca/profile/DuncanJStewart](http://www.ohri.ca/profile/DuncanJStewart))

Vice-president, Research, The Ottawa Hospital

CEO and Scientific Director, Ottawa Hospital Research Institute

Professor of Medicine, University of Ottawa

*Dr. Stewart is a cardiologist and stem cell researcher. He has conducted clinical trials using stem cell therapy for cardiac patients. He also sits on the Board of Directors of the CPSR.*

While no stem cell trials are currently underway in Canada to promote recovery from stroke, plans are in development for a national study led by the Heart and Stroke Foundation Canadian Partnership for Stroke Recovery. The hope is to

have a study launched by 2017. The study would involve the use of adult stem cells. These are cells found throughout the body that have the ability to divide indefinitely and produce the different kinds of cells that maintain the body's tissues and organs.

Please read further to get the answers (unfiltered and straight from the experts' mouths) to your FAQs about stem cells and stroke recovery. However, please note that your own health care provider is the best person to provide medical advice tailored to you.

For more information, visit: <http://closerlookatstemcells.org>

### **Transcript of Interview with neuroscientist Dr. Dale Corbett**

#### **Q: How common is stroke?**

**A:** Stroke is a very big problem. Last year we commissioned a study to measure the scope and we found that there are about 62,000 strokes per year in Canada and there are more than 400,000 people who are living with long-term disability from stroke. It's predicted, based on our study, that by the year 2038 the incidence of stroke in Canada will nearly double. Just to give you some idea of what that would be like, just imagine that in 2038 that every single person in Ottawa had a stroke. That's the size of the problem that we're going to be faced with.

#### **Q: What's the aftermath of stroke?**

**A:** The aftermath of a stroke includes many different deficits. It could be in language. It could be in cognition or learning and memory. It could be in the ability to use our limbs, upper limbs or lower limbs. It could affect our moods.

#### **Q: What does the public need to know about stroke?**

**A:** The general public needs to know that stroke is a huge problem. They need to know the warning signs of stroke and to get to a hospital in time. And they need to start doing things in their lives to help prevent a stroke like maintaining a healthy blood pressure, being physically active, eating a healthy diet and so on.

#### **Q: What are the most common questions you get about stroke recovery?**

**A:** Some of the most common questions I get include: 'What can we do to improve our recovery? What about stem cells? Are they ready to be given to patients? Are they safe and could we benefit from stem cell therapy?'

#### **Q: And what is your answer to questions about the use of stem cells for stroke recovery?**

**A:** I say that it is a little early yet. We still need to do a bit more research but, based on what we do know, we think we will go ahead and do a small trial here in the next year or year-and-a-half. Stem cells appear to be safe and we think it's time to do these kinds of trials in Canada.

**Q: More specifically, what kinds of studies would you like to start here?**

**A:** There are a number of studies that need to be done to increase our understanding of stem cell therapy and stroke recovery. One of the most important studies to be undertaken would look at when to administer the stem cells. We know that other treatments and interventions, if given too early, can actually make things worse. The same might happen with stem cells. On the other hand, if you leave it too long they may not be as effective. Right now the time window that seems to be optimal with other interventions or treatments is about 5 to 14 days after the stroke. But an interesting idea with stem cells is they may also be beneficial if given to patients after their recovery has stalled or plateaued. This would be at about 3 or 4 months after the stroke. It's possible, we don't know, but it's possible that stem cells given that late may also be effective. We're going to be starting a clinical trial here in Ottawa testing that very idea in the coming year or two down the road.

**Q: Why are researchers investigating stem cells to boost recovery?**

**A:** Stroke recovery is the new frontier in stroke research. It's the area of research that offers the most hope to the greatest number of patients. What we're doing in our own research in the Canadian Partnership for Stroke Recovery is we're using a variety of approaches to enhance recovery. One of the approaches is stem cell therapy and we think that it has a lot of potential to improve recovery in people and help them achieve a fuller recovery by reorganizing and rewiring the brain, enhancing what we call brain plasticity and improving function.

**Q: What kind of research is underway now in Canada?**

**A:** In Canada there is quite a bit of research on the pre-clinical side with stem cells and stroke recovery but there's not anything taking place with regard to clinical trials in patients. Around the world presently there are about 35 different trials taking place with stem cells, but not a single one here. We're hoping to change that in the Canadian Partnership for Stroke Recovery in the next year or two and we'll initiate the very first trial here in Canada.

**Transcript of interview with stroke neurologist Dr. Dar Dowlatshahi**

**Q: You see a lot of stroke patients. What's the top question they ask you regarding stem cells?**

**A:** The most common question I get regarding stem cells is, first of all, do they work? Second, where can they get them?

**Q: And what's your answer?**

**A:** It's a very hard question. What I usually tell them is I'm hopeful they work. We don't know for sure if they work is the honest answer. Probably there will be a time – it could be in the near future – where we're going to get stem cell therapy working for stroke recovery. But right now the treatment isn't at that stage yet. Right now we're looking at some preliminary trials [in other countries] all of which

have been flawed unfortunately. What I try and tell the patients is we need more time, we need to do more science and, most of all, we need to do this safely and ethically.

**Q: What's the flaw with the current studies today?**

**A:** There are a lot of questions around how to use stem cells for stroke recovery. There are questions that haven't been addressed yet. For example, what type of stem cells should we be using for stroke. We have many we can choose from and we don't know which ones are going to work. Second question is: how do we give the stem cells? The ideal way is through an injection that doesn't require any major surgery and that would be the safest. But we don't know if that will work. Other people are advocating doing open surgery, which is a very risky proposition and may also not work and do harm. The third question is: what type of strokes? Stroke is not a single disease. It's many different diseases with many different recovery patterns, many different symptoms. So, we don't know which ones will respond to what type of stem cells. And another important question is: when do you give the stem cells? There have been studies that gave the stem cells too early thinking 'we want to get in there right when people are recovering.' The problem with that is many patients are quite sick at that stage and there can be a lot of complications with the therapy. The second issue is some patients with stroke are very fortunate and get better very quickly on their own just through regular physical therapy. In fact, I'd say many patients with stroke do. That's the rule of stroke. It gets better. So those studies failed to show any benefit -- not necessarily because the stem cells didn't work but because the patients got better on their own, even the ones who never received the stem cell therapy.

**Q: It seems like you're not very impressed with the current studies?**

**A:** The current studies are extremely flawed. When we put them together, we did get some useful information. We learned what not to do and we also learned there is a risk.

**Q: What do we need then?**

**A:** What we need is better designed studies, done in a reproducible manner. What I mean by that is good, solid, experienced research teams. And what we want to do is get the right patients tested -- we should open it up to as many patients as possible but in their own specific studies. So, we should design trials for patients who are maybe at 3 to 6 months in their recovery after stroke, maybe some who are longer than 6 months. We want to design studies for the bleeding strokes. We want to design other ones for the clotting strokes. I think we should not so much take our time, but do it right.

**Q: How is our country positioned to do that kind of research?**

**A:** The unique thing about Canada is we have terrific scientists, we have a lot of motivation and we have a health-care system that eliminates a lot of the problems, a lot of the financial incentives that a lot of other systems face. What

that translates to is we genuinely have smart people who can do things right and want to do things right. I think we have all the talent to do a stem cell trial and right now would be a fantastic time to launch a stem cell study for stroke.

**Transcript of interview with stem cell expert Dr. Duncan Stewart:**

**Q: How are stem cells used to treat a stroke?**

**A:** This is a research area -- it's experimental -- so we don't have standard stem cell treatments for stroke. But the idea is that stem cells will help the brain heal and recover from stroke either by replacing brain cells that have been damaged during the stroke or by improving the natural healing ability of the body, improving the ability of the brain to adapt to a stroke.

**Q: What could stem cell therapy mean for patients?**

**A:** It could mean a better recovery. The hope would be that patients would get better use of their limbs, for example, if they have lost the ability to use a limb. Or better ability to recover their speech faculties and so forth.

**Q: Are stem cells safe?**

**A:** Like any new therapy, we don't know for sure. We don't have a lot of time of experience with stem cell therapy. But what we do know so far is that adult stem cells have been remarkably safe. In the studies that have been done [to treat other diseases], which have obviously looked very carefully at various safety issues, and there really has been no signal that the cells we are using now are causing any problems, which is very encouraging.

**Q: What about the long-term risks? What do you know about that?**

**A:** There are theoretical risks with any therapy. A major concern is that they could grow in a way that's uncontrolled. You put a stem cell in and, maybe, instead of doing what you want it to do, you could produce a tumour. That would be a major concern. But, as I said, the field has looked very carefully at this and really there has been no indication that the adult stem cells that we use and the way that we use them poses this kind of risk.

**Q: What do you know about the current application of stem cells outside of Canada?**

**A:** There are other jurisdictions -- Europe, Asia, U.S. that are interested in this field -- so there are a lot of groups that are moving forward with stem cell trials for various diseases. I think it's fair to say that in Canada we have some advantages. We were the birthplace of stem cell research. Stem cells were discovered here in Canada and, partly because of this, we've had a very strong scientific community in the area of stem cells. So, I think we have a great opportunity to move this forward. Obviously, we're smaller in terms of population than many countries, but we are certainly a major part of the international effort.

**Q: What is your caution to patients who are looking abroad for stem cell therapy for stroke recovery?**

**A:** I make a big distinction between trials and studies that are going on within bona fide academic environments, which are properly designed and properly approved by regulatory authorities, and treatments that are being offered by private companies often completely outside of any regulatory framework and not being overseen by the equivalent of our Health Canada, for example. And the latter groups are really for-profit. These are private companies that are out there to make a profit. They are charging a fair bit of money for an unproven cell therapy and, very often, with no controls as to what they are actually delivering – whether the cells are active, whether they do what their claims say they do, in fact, whether the cells are even in a good condition, whether they're even alive. This is a problem. Patients would go there, they would definitely be parted from their money. What they receive, we don't know. If they receive a product that is not good, that does not have good quality controls, it may be contaminated, there may be other things in that product, then that raises concerns.

**A: What are the key research questions you have related to stem cells?**

**Q:** There are a number of questions. A big question would be 'how do stem cells work?'. When we began the field of stem cell therapy, we thought very simply that stem cells would be building blocks, that they would produce new cells to replace damaged cells in the brain or other tissues. And while they can do that, I think some of the benefits we're seeing in the animal models and our pre-clinical research, as well as in the clinical trials that have been done in other areas, are not due to that direct mechanism. Probably these cells have an ability to promote healing indirectly: modify the environment within the tissue that's been damaged, reduce the degree of inflammation, and promote an environment that is more conducive to healing. They may also stimulate the stem cells that reside in these tissues, to awaken them and make them more active in the healing process. In the cells we're using now, that seems to be the way they're working.

The other questions that are also very important are: how to deliver and when to deliver stem cells? These are simple things but they are incredibly important and they can mean the difference between a therapy that works and a therapy that doesn't work. So, for example, when we first started doing this in the heart, we wanted to get those cells in there as soon as possible after the heart attack and we found out actually that doesn't work well because the environment soon after that kind of damage is very hostile. The cells don't have enough oxygen. There's not a good place for them to adhere to and survive. We found that if we wait a few days the blood supply improves within the area, the healing begins and the area is more receptive to the stem cells. So you can think of it a bit like planting seeds in the soil. If you plant in soil that is dry, which is not prepared, it's too hard or too hostile, then the seeds won't germinate. If you plant in soil that is ready then, of course, they'll do well. It's a bit the same.

**Q: What kinds of studies do you need to develop?**

**A:** We need to do more studies to address when is the best time to deliver these cells and how best to deliver them. If we deliver them too early, we might not get the right result. Maybe we need to wait a few days, a few weeks, maybe even months. We also need to understand what is the best way to deliver them. Some studies have injected them directly into the brain or into the spinal fluid around the brain. Others have given them intravenously. We don't know which approach is going to be the most effective. And this is why we really need to do more research.