



I love stem cells

MEDICAL TOURISM

THE POTENTIAL DANGERS



CellCAN

Regenerative Medicine and
Cell Therapy Network



STEM CELLS

THE **POTENTIAL DANGERS** OF MEDICAL TOURISM

You've no doubt heard media reports about individuals who travel outside of Canada for "miraculous" stem cell treatments, also known as cell therapy. Far from always providing the desired results, "**stem cell tourism**" may actually **put your health and your bank account at risk!**

THE REALITY

UNPROVEN RESULTS

Many clinics worldwide offer stem cell treatments, but the efficacy and safety of these treatments have not been scientifically proven or have not received regulatory or ethics approval. Some of these treatments can be harmful to patient health.

While a number of cell therapy treatments are available for which the efficacy and safety have been proven (such as therapy for blood cancers), a lot of research on stem cells is still at the laboratory or initial clinical-trial stage.

As for all medical treatments, stem cell therapies must first be tested on animals and then humans to demonstrate both their efficacy and safety. The results are then reviewed by regulatory authorities for approval before being administered to the public.

WHAT ARE THESE TREATMENTS?

Stem cell tourism clinics may offer treatments for:

- Multiple sclerosis
- Diabetes
- Spinal cord injuries
- Autism
- Cerebral palsy
- Blindness
- Parkinson's disease
- Sports injuries
- Back pain
- Aging
- Hair loss
- Various cosmetic procedures

The stem cells used for these treatments can come from patients themselves, other adults, umbilical cord blood or embryos. The cells are transplanted through surgery; blood, skin or muscle injections; topical skin applications; or oral ingestion.

HOW TO RECOGNIZE FRAUDULENT CLINICS

Typically, fraudulent clinics emphasize the benefits of cell therapies and omit or minimize the associated risks. They may provide scant evidence of effectiveness and safety but ample positive patient testimonials. For various reasons, it can be hard to find scientific publications about the offered therapies.

These clinics are often located in countries where legislation does not adequately protect patients. Medical tourism clinics have been reported in China, Mexico, India, Panama, Ukraine, Russia, Costa Rica, the Dominican Republic, Thailand and the Philippines. Even in the United States, some clinics have found ways to circumvent laws and regulations to offer unproven treatments.

! BE VIGILANT
Below you'll find more information to help you recognize a fraudulent clinic.



BIASED ADVERTISING

An advertisement is biased when the risks are minimized or hidden while the benefits are heavily emphasized. The ads may also focus on the emotional and even humanitarian aspects of these stem cell therapies (whose effects have not been proven).

These alternative treatments may have received regulatory approval in these countries. But this does not mean that their effectiveness is proven. **You should always ask for clinical scientific evidence of the effectiveness and safety of the treatment (e.g., publications in peer reviewed scientific journal). Your doctor can help you understand and evaluate them.**



FALSE CLINICAL TRIALS

If the clinic claims that the procedure is “experimental”, then this could mean you would be taking part in a clinical trial. A true clinical trial must:

- ✓ Be registered and have a clinical study number
- ✓ Have strict admission criteria
- ✓ Have received approval from regulatory and ethics authorities
- ✓ Be provided at no cost to participants
- ✓ Provide specific information to participants before they start the trial, such as the:
 - study design
 - study procedure
 - risks and benefits
 - alternatives outside of the clinical trial

If this information is not provided, the clinical trial may not be legal. The following database is a registry of clinical trials conducted around the world: clinicaltrials.gov



PATIENT TESTIMONIALS WITHOUT SCIENTIFIC EVIDENCE

Instead of scientific evidence, these clinics often use patient testimonials to demonstrate the effectiveness of their treatments. Despite the good intentions of the people telling their stories, a testimonial is not proof. Indeed, sometimes patients want so badly for the treatment to be effective that they may feel it actually is. These effects, even if they are real, may not continue over time or may result from something other than the treatment.

To evaluate treatments, scientists do use patient testimonials, but they also base their evaluation on objective evidence, such as blood tests, biopsies, medical imaging or other tests.

If a clinic tells you that its research is not yet published because the treatment is patent pending, then beware, as the claim is probably false. In fact, as soon as a patent application is filed, the idea is protected, and scientists generally publish their findings because they require other scientists to reproduce their results and validate them.



STANDARDIZED INSTEAD OF PERSONALIZED TREATMENTS

Many clinics that offer unproven therapies also have the following characteristics:

- They use a single type of stem cells
- They always use the same transplant procedure (e.g., blood injections)
- They claim they can treat a wide range of diseases and injuries because the stem cells will travel to the site of the injury or disease

In reality, each disease has its own characteristics. **For a treatment to be effective, the type of cells and the transplant procedure must be adapted to each case.**



HIGH COSTS AND MULTIPLE TREATMENTS

Many of these clinics offer therapies that require multiple treatments and at considerable expense. In fact, reports indicate that these clinics can charge between \$5,000 and \$30,000 (or more). Although real clinical trials may have some associated costs (such as travel expenses), patients do not have to pay for treatment.

You also need to consider a number of other money-related factors when it comes to medical tourism. For example, you may run into unforeseen costs, especially in the case of complications.

- Would your personal health insurance cover emergency care? Or would the clinic where you receive the stem cell treatment cover this care?
- Where and how will you receive any subsequent care? You need to answer these questions before resorting to medical tourism.

WHAT ARE THE RISKS OF THESE TREATMENTS?

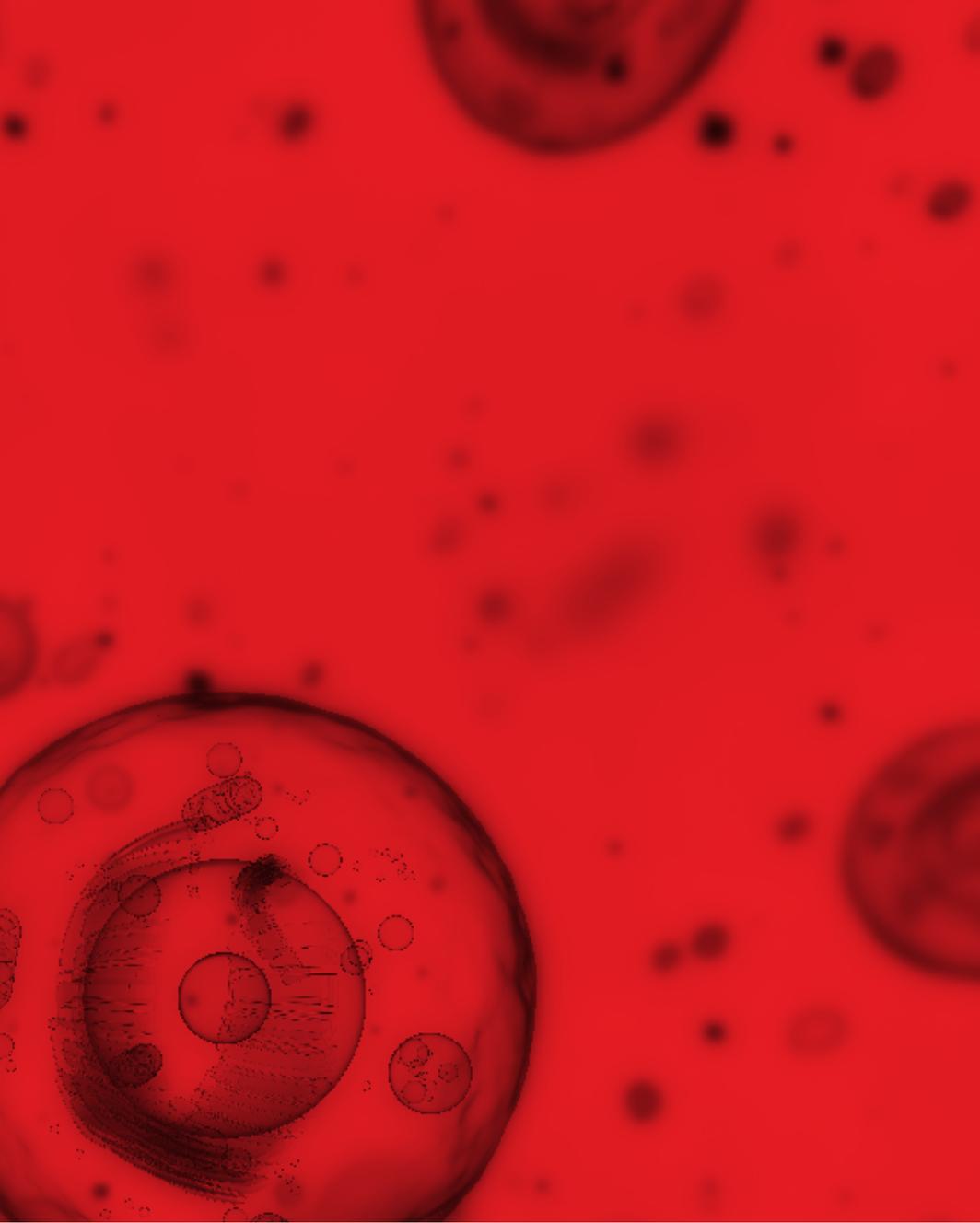
Many patients who seek out cell therapy think they have nothing to lose, whether the therapy has been proven or not, but this isn't true. Therapies without any demonstrated efficacy or safety can still be dangerous, worsen the overall health of patients, and even put their lives in danger.

The stem cells may be contaminated with bacteria, viruses or fungi, even if they are taken from patients themselves in a sterile environment (such as an operating room). Stem cells taken from another individual pose a risk of immune response, i.e., when the patient receiving them reacts to these foreign cells. Some patients who receive unproven treatments develop lesions, tremors, tumours or cancers, and these side effects can result in death. In addition, anesthesia and the transplant procedure itself also pose risks.

Patients should also know that receiving these treatments could prevent them from participating in legitimate clinical trials here in Canada, where eligibility criteria are very strict.

The time required to develop treatments can seem incredibly long to patients who have incurable or debilitating diseases. But scientists, doctors and regulators are concerned about everyone's safety and well-being and must ensure that treatments will actually improve a condition and not cause additional problems (e.g., severe side effects). **To expedite the availability of cell therapies, efforts are constantly made to improve and streamline the regulatory process.**

Before getting any treatment, you should always talk to your doctor about it and don't hesitate to send us any questions you might have at helpdesk@cellcan.com



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