

Medicine's wild east

It's a stem-cell therapy untested and unproven for many incurable diseases, but under China's little-regulated system, hospitals are cashing in on the last-chance hopes of the desperate and the dying with tissues and cells harvested from aborted fetuses' brains and tissues amid the country's one child policy and forced abortion.

The Singaporean doctor has amyotrophic lateral sclerosis (ALS), the incurable degenerative disease of the nervous system. He tried the drug with the best chance of slowing the weakening of his muscles, the compromising of his respiratory system, the steady onset of death. But he is allergic. He figured he had only one hope left.

Dr Poon Lee Kwee, 61, joined the droves of foreigners now flocking to Chinese hospitals for stem-cell treatments - therapies that are untested and unproven, but China's little-regulated climate, are offered far more freely than in the United States and other Western countries.

Seven months after being diagnosed with ALS, the general practitioner paid US\$20,000 for a month-long therapy in Guangzhou in March. Poon received six injections of mesenchymal stem cells (MSCs), a kind of adult stem cell from umbilical-cord blood, at Guangdong Provincial Hospital of Traditional Chinese Medicine.

The treatment has undergone no clinical trials, yet the hospital's website claims that a wide range of conditions considered incurable by other means are now treatable with its revolutionary stem-cell therapy - from the fatal ALS, cerebral palsy, autism, Parkinson's disease, spinal-cord injuries, and optic-nerve disorder to foot ulcers caused by diabetes.

Hu Xiang, chairman of Shenzhen-based Beike Bio-Technology, the injections' maker, said the treatments with stem cells extracted from umbilical cord blood were offered by more than 50 mainland hospitals and had been injected into more than 10,000 foreign patients from 70 countries.

For the hospital's claims to come true 'would be a miracle', said Marius Wernig, principal investigator at Stanford University's Institute of Stem Cell Biology and Regenerative Medicine. That's because MSCs only have a very limited capacity to make scar, bone and fat, but not organs or neural stem cells despite what hospitals claim.

In Beijing's military hospitals, 'miracle treatments' are also offered in a brave way with cells cultivated from aborted fetuses' brains and tissues being injected directly into patients' brains and spines. Similar fetal-cell treatments are given at the Naval General Hospital of PLA, the General Hospital of Chinese People's Armed Police Forces, Peking University

Health Science Centre and many other public hospitals.

An injection of stem cells from the brain of a fetus offered at 12,000 yuan (US\$1,854) at the Naval General Hospital of the PLA in Beijing. A Shanghai father who paid 18,000 yuan for a treatment for his son with cerebral palsy said he believed cells were taken from induced abortion. 'Otherwise you never know whether the cells from spontaneous abortion are good enough to repair injuries,' he said.

In two articles in the Second Military Medical University's journal, Tian Zengmin, the naval hospital's neurologist, detailed how they cultivated fetal brain cells taken from five- to 11-week-old fetuses to treat Parkinson's disease and cerebellum atrophy. His research was funded by the Chinese government.

An Yihua, director of the stem-cell transplant department at Beijing's General Hospital of the Chinese People's Armed Police Forces, told People's Daily that Chinese hospitals had been using fetal brains to treat patients since the 1980s, and a huge number of patients received similar treatments during the past three decades. An's hospital alone has treated nearly 4,000 patients with its neural stem cells since 2003, including foreign patients from 20 countries.

Research projects using embryonic and fetal stem cells are ethically controversial in the West and have generated plenty of public debate, but in China there is little discussion and public opinion seems to be largely positive. China's 'one child' policy has ensured, although unintentionally, that the supply of fetal stem cells would be limitless.

Many Chinese mothers-to-be are forced to terminate their pregnancies, regardless of the stage at which they are, under this policy. Authorities exert pressure to abort by imposing heavy fines on would-be parents, dismissing them from jobs, and refusing residency permits and social protections such as education and medical services for the children.

After the abortion, the hospital often sells the fetal tissue to other hospitals or laboratories for stem-cell research or treatment, without the mother's knowledge due to the country's lax system of ethical and regulatory oversight and respect to privacy.

Chinese stem-cell researchers will not say publicly where the fetal tissue they used for study or treatment comes from. A close reading of mainland journals show that many cells used for the research are coming from induced abortions, with fetuses range in age from five weeks to six months.

In fact, fetal stem cells and tissue from abortion clinics have become a steady source for mainland hospitals in treating patients for various diseases as early as 2000, as well as stem-cell laboratories for research.

'Generally, surgeons in China are very likely to use aborted fetuses in medical

experiments and treatments without informing the mother-to-be,' Liu Hongbo, a noted newspaper columnist said, 'Many Chinese mothers-to-be are also not aware of their rights on aborted fetuses, and some surgeons take advantage of this.'

He said Chinese legislators only regard babies, not fetuses, as human. 'Chinese authorities believe fetuses are just a possibility of life, and abortion is legal and well accepted by the public.'

Ding Yu, a researcher from Sun Yat-Sen University who specialises in women's rights, said: 'Very few Chinese have ethical concern over abortion after three decades of the 'one-child policy' and forced abortions. Most of them take induced abortion as common phenomena and never link this with human rights or a fetus' right to life.'

In Shenzhen, public hospital obstetricians said that in most cases, a mother-to-be will leave the aborted fetus or stillbirth baby to the hospital as medical residue. The fetuses will be sold. And so will the placentas, to pharmaceutical factories or individuals who believe them rich in nutrients and suitable to eat.

Chinese media revealed that a Liaoning woman who chose a sex- selective abortion in Xi'an in Shaanxi province in June last year discovered that her six-month-old fetus was sold to a local medical company focuses on producing artificial skin and cornea. Three maternity assistants who sold the fetus soon after the abortion were fired by the hospital after a police investigation.

Actually, manufacturing one injection of the MSCs or fetal stem cells can cost as little as 300 yuan, according to an investigation by China Central Television. And these cells could never cure the desperate patients' disease.

US-based International Society for Stem Cell Research said there are still many barriers to the development of successful stem-cell therapies. Among them: getting the cells to behave in the desired way. 'We are still learning about how to direct stem cells to become the right cell type, to grow only as much as we need them to,' the ISSCR said.

Wernig said there were some clinical trials using fetal brain tissue in the United States, in particular in patients with Parkinson's disease. '[But] the success rate was very limited and led to uncontrollable severe side effects,' he said. 'Scientists are trying to find out why the transplants did not lead to the desired effect. "

Beijing has poured billions of yuan into the research hoping to find innovative cures to chronic and deadly illnesses as leaders see stem-cell research as an area in which the country's biotechnology industry might outpace the West.

The 973 State Development Programme for Key Basic Research will invest 1.6 billion yuan in stem-cell research and five other fields this year, while the 863 State Hi-Tech

Development Plan will allocate 130 million yuan for developing potential treatments for heart disease, liver failure, Parkinson's disease and repair of neural conditions.

Many mainland hospitals are not waiting for clinical approval, and the ballyhoo is attracting thousands of desperate Chinese and foreigners ready to pay for treatments that are untested and successes are sketchy at best.

A 30-year-old man from Jinhua city in Zhejiang province with cerebral infarction died four days after receiving two stem cell injections from the No. 455 Hospital of PLA in Shanghai in July. The victim's elder brother, Hong Chun, had received anonymous calls from Guangdong threatening him not to expose the malpractice.

Yu Shuangfeng, 68, is among 21 mainland patients who have sued the military hospital for fraud. Yu said she nearly died of strong side effects, including fever, after paying 70,000 yuan for two injections last year. Her diabetes has never been cured. Instead, it worsened.

"All of these stem cell therapies are still at the research stage, and none of them has been approved by domestic health watchdog as effective treatment," Chinese Academy of Science academician Wu Zuze said.

Professor Ronald Li, director of Hong Kong University's Stem Cell and Regenerative Medicine Consortium, said almost all stem-cell therapy worldwide were still in the experimental stage or clinical trials.

'Many hospitals and centres have obviously overstated their stem cell treatments, with very bold claims,' Li said. 'Too much hype is going to jeopardise a paradigm-shifting field. We need to distinguish facts from hype. The field needs time and space to grow and mature - it will happen, but not right away.'