



STEM CELL THERAPIES

Research and clinical trials; overseas buying and selling

Stem cells have substantial potential to make a major contribution to new therapies for many currently untreatable conditions, and indeed they have already been employed in selected medical conditions – for example to repopulate the bone marrow following treatment for some haematological malignancies, and more recently for wound healing. A number of carefully-controlled trials exploring stem cell therapies in cardiac disease, all carrying full regulatory approval, are also currently underway, earlier studies having shown promising results. There is real hope that stem cell therapies may eventually provide disease-modifying therapies for a number of neurological diseases including conditions such as Parkinson's disease, Huntington's disease, multiple sclerosis, and stroke.

The ABN believes that it is extremely important to pursue stem cell research. There are significant biological challenges to be overcome before stem cell therapy is ready for any form of routine clinical application in neurological disease. Moreover, there are also serious potential safety issues associated with some forms of stem cell therapy, including tumour formation and transmissible disease, which have yet to be satisfactorily addressed. It is important, therefore, that when stem cell therapies are tested in patients, it is only in the context of an ethically approved and properly regulated clinical trial. If 'treatments' are given without such independent approval, and outside the regulatory framework, patients are at risk at best of being exploited, and at worst of exposure to serious medical risks.

Until treatments are properly established they should not take place outside a clinical trial. We would not expect patients to have to pay to take part in such a trial.

Many patients with multiple sclerosis (or their carers), and some with other neurological diseases, have enquired about the possibility of travelling to continental Europe, or elsewhere, to buy some form of stem cell therapy, usually for costs up to £20,000. A number of companies, usually with a prominent internet presence, are selling 'treatments' as a purely commercial activity. At least in the context of multiple sclerosis, these companies selling such therapies are not carrying out detailed neurological examinations at different intervals before and after the therapy, or scanning before and after therapy, to try to prove benefit (or check for harmful side effects). They make no effort to contact the patient's usual doctors to confirm the diagnosis, or check previous and current other treatments, etc. In short, they are acting wholly outside the usual regulatory and ethical frameworks.

When vulnerable patients are given enormously high and wholly unrealistic expectations, and when large sums of money change hands, for so-called "therapies", there is a very real risk of exploitation. We strongly advise patients (or carers) considering such treatments to discuss them with their physicians and to establish the reputation of the establishment offering treatment before proceeding.

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