

Opinion concerning intracerebral transplants of mesencephalic tissues from human embryos to five patients with Parkinson's disease for the purpose of therapeutic experimentation.

N° 23 - December 13, 1990

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The National Consultative Ethics Committee has received a request for an opinion concerning " authorization to practise intracerebral transplants of mesencephalic tissue from human embryos to five patients with Parkinson's disease, for the purpose of therapeutic experimentation" .

In October 1989, the Committee recommended " that, at least for the time being, attempts to treat Parkinson's disease by transplantation not be undertaken in France" . This unfavourable opinion was essentially based on medullo-adrenal autotransplantation, whose danger is unquestionable, but whose effectiveness is doubtful. In so far as transplants of human embryo tissue are concerned, it was then specified, that, " in the event, that technical difficulties associated with the preparation of mesencephalic cells from human embryos are overcome, and that the transplantation of such cells leads to appreciable and sustained improvement, objections of an ethical nature would no longer apply" .

Since that time, new scientific information has become available, due mainly to Lindvall's Swedish research team:

- the demonstration that, in patients with Parkinson's disease, transplants of embryonic mesencephalic tissue can release dopamine (labeled dopamine detected by positron emission tomography, after injection of radioactive fluorine labeled DOPA);
- clinical improvement observed in several patients after such transplants.

In addition, the risk to the patient resulting from stereotaxic implantation is relatively low.

As of this writing, the number of patients with such transplants, who have been studied seriously, is very small (moreover, the time involved is relatively short).

This justifies the new project, submitted to the Committee by a multi-disciplinary team, built around the neurology and neurosurgery departments of Henri Mondor Hospital in Créteil. As part of a cooperative effort, involving various European teams working in an analogous manner, the French project has the objective of evaluating the therapeutic action of embryonic tissue transplants in five patients, whose course will be monitored over several years.

The Committee recalls that the sampling of embryo cells will have to meet the requirements of the Opinion of 22nd May 1984, and in particular, the relevant deontological and medical directives.

- The decision and the conditions (date, technique, etc.) of the pregnancy termination must not be influenced, in any way whatsoever, by the possible or desired subsequent use of the embryo or fetus. If the vacuum technique is chosen, this must be on the basis of exclusively obstetrical criteria, and with a view to safeguarding the woman's child-bearing potential.

- Complete independence must be established and guaranteed between the medical team responsible for the elective abortion, and the medical team likely to use the embryos or fetuses.

Provided these conditions are met, a favourable opinion is given for this therapeutic experimentation project, as limited to five patients.

The Committee wishes to be kept informed as to the clinical course of these patients, both in terms of their Parkinson's disease, and of possible side effects of treatment to prevent transplant rejection.