Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

THE CELLULAR THERAPY OF HUNTINGTON'S DISEASE THROUGH THE IMPLANTATION OF FOETAL NEURONS

(20th May 2005)

abstract

The NBC has responded to the question raised by Dr. Alessandro Nanni Costa, the Director of the National Transplant Centre regarding the ethical problems concerning the source of the cells used in the multicentre research trial "The cellular therapy of Huntington's disease through the implantation of foetal neurons" in which the National Neurological Institute "Carlo Besta" is participating.

Huntington's chorea affects primarily the degeneration of an area of the brain called "striatum"; it is situated in the basal area where the "central command system" that coordinates body movement lies. There is no effective treatment for this disease today. However, numerous clinical trials on mice, rats and non-human primates have demonstrated that transplanted foetal striatal neurons are able to restore the clinical deficit on animals with induced neurodegenerative lesions. On the whole, the clinical trials confirm the therapeutic potential of the grafts of homologous foetal neurons in the case of induced neuron degeneration in the animal models with Huntington's disease.

The question raised and referred to the NBC regards an evaluation of the ethical problems connected to the origin of the cells used in this particular project; however, it does not include an ethical evaluation of voluntary interruption of pregnancy. Nevertheless, the NBC is concerned that voluntary interruption of pregnancy must not, in any way, be used to intentionally produce foetal tissue for experimental and/or therapeutic purposes. Therefore, the Committee considers that the retrieval of foetal tissue from voluntary interruption of pregnancy and its use for the aforesaid scientific and /or therapeutic purposes are to be regarded as "morally acceptable practices", only, when complying with the following conditions:

1. there should be a distinct separation of respective decision-making between the medical staff and/or the health institution carrying out the voluntary interruption of pregnancy and the researchers and/or the research institutes conducting the scientific and clinical experimentation;

2. there should be no advantage, incentive or benefit of any form for those involved, that is, the medical staff and/or health institution carrying out the voluntary interruption of pregnancy and the researchers and/or the research institutes conducting the scientific and clinical experimentation;

3. the woman's consent, and where possible, that of both the parents, should be obtained after being adequately informed. This consent should only be requested after the voluntary interruption of pregnancy has taken place, in order to prevent that the foreseen use of foetal tissue for scientific and/or therapeutic purposes might constitute an undue inducement to resort to this practice;

4. the method and procedures of the voluntary interruption of pregnancy should not undergo modification or modulation, in relation to the need to retrieve foetal tissue and the scientific or therapeutic purposes. No preventive treatment functional to the scientific or therapeutic purposes of the use of foetal tissue may be carried out on the woman and/or on the foetus during the course of the pregnancy;

5. the right to privacy of the woman should be guaranteed by the laws in force;

6. the use of foetal tissue should only be for highly important scientific and/or therapeutic purposes for which no alternative methods with comparable requirements exist. In any case, where possible, it is always preferable to resort to foetal material from miscarried foetuses rather than from voluntary interruption of pregnancy;

7. each project which foresees the retrieval of foetal tissue, deriving from voluntary interruption of pregnancy or miscarried foetuses and its use for scientific and/or therapeutic purposes, should be subjected to preventive ethical evaluation on behalf of the relevant competent committee;

8. the donation of foetal tissue from interruption of pregnancy or miscarried foetuses for scientific and/or therapeutic purposes should not involve any form of commercialization, remuneration or compensation.

With regard to this last point, the NBC hopes for intervention on a national and European level, in order to impose a ban on the commercialization of foetal cells and tissues deriving from voluntary interruption of pregnancy or miscarried foetuses as soon as possible by means of specific and unambiguous regulations which consent to counter the growing and concerning phenomena of “foetal tissue brokers”.

The opinion is accompanied by a personal remark.