Statutory Approvals Committee – minutes

Centre 0119 (Birmingham Women's Hospital)

Pre-implantation Genetic Diagnosis (PGD) application for

Cerebral Cavernous Malformations 3, OMIM #603285

Thursday, 25 May 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Margaret Gilmore (Chair) Anne Lampe Ruth Wilde Anthony Rutherford Bobbie Farsides	
Members of the Executive	Bernice Ash Paula Robinson	Secretary Head of Planning & Governance
External adviser	Dr Jenny Carmichael	
Legal Adviser	Sarah Ellson	Fieldfisher
Observers		

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

The following papers were considered by the committee:

- Executive Summary
- PGD Application Form
- Redacted peer review
- Genetic Alliance opinion
- Licence Committee Minutes

1. Consideration of application

1.1. The committee welcomed the advice of its specialist adviser, Dr Jenny Carmichael, who confirmed that the condition was as described in the papers.

1.2. The committee noted that the description in the PGD application for Cerebral Cavernous Malformations 3, OMIM #603285 is consistent with the Peer Review.

1.3. The committee noted that the Genetic Alliance opinion provided a patient perspective and supported the application.

1.4. The committee had regard to its decision tree. The committee noted that the centre is licensed to carry out PGD. The committee was also satisfied that the centre has experience of carrying out PGD and that generic patient information about its PGD programme and associated consent forms had previously been received by the HFEA.

1.5. The committee noted that the condition being applied for is not on the list of approved PGD conditions.

1.6. The committee noted that the proposed purpose of testing the embryos was as set out in paragraph 1ZA(1)(b) of Schedule 2 of the Act, i.e. 'where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality'.

1.7. The committee noted that the condition is an inherited in an autosomal dominant manner which means there is 50% chance of having an affected child in each pregnancy, if either parent has a relevant mutation.

1.8. Cerebral Cavernous Malformations 3 (CCM3) causes cavernous malformations to occur, formed from groups of small blood vessels, known as capillaries, which become enlarged and irregular in structure. As a result, the capillaries often leak, which can cause a series of health problems. Usually the most serious effects are caused by these capillaries leaking in the brain and, or spinal cord (which are known as cerebral).

1.9. The committee noted that some individuals with Cerebral Cavernous Malformations never have a health issue related to the condition. However, many people experience brain haemorrhages causing serious symptoms such as hearing or vision loss, headaches, seizures and paralysis. Severe brain haemorrhages can result in death.

1.10. Symptoms may appear at any stage throughout life, from early infancy to adulthood. CCM3 is the least common but most severe and aggressive form of CCM.

1.11. The committee noted there is currently no curative treatment for the condition. Surgery to remove lesions, which are not located in critical brain regions, may be considered but does carry risks. Treatment of seizures, epilepsy and headaches is symptomatic.

1.12. The committee noted the inspectorate’s recommendation to consider the approval Cerebral Cavernous Malformations 3, OMIM #603285 to be included on the PGD List. The committee agreed to consider the application on this basis.

2. Decision

2.1. The committee considered Cerebral Cavernous Malformations 3, OMIM #603285 is serious given the early onset and effects on quality of life of this condition, including brain bleed, psychological impact and the lack of a cure, noting the condition is effectively a ‘ticking time bomb’. The committee considered the impact on the individuals’ quality of life and the family caring for affected individuals.

2.2. The committee noted that the condition is consistent with Cerebral Cavernous Malformations, OMIM #116860, approved in 2010.

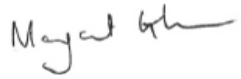
2.3. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition. The committee was therefore satisfied that the condition of Cerebral Cavernous Malformations 3, OMIM #603285 does meet the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act.

2.4. The committee agreed to authorise the testing of embryos for Cerebral Cavernous Malformations 3, OMIM #603285.

3. Chair’s signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Margaret Gilmore

Date

8 June 2017