Statutory Approvals Committee - minutes

Centre 0102 (Guy's Hospital) – PGD application for Centronuclear Myopathy (DNM2-related), OMIM #160150

Thursday, 24 November 2016

HFEA, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Rebekah Dundas (Deputy Chair) Anne Lampe Ruth Wilde	
Members of the Executive	Siobhain Kelly Trent Fisher	Head of Corporate Governance (interim) Secretary
External adviser	Professor Mary Porteous	
Legal Adviser	Graham Miles – Blake Morgan LLP	
Observers	None	

Declarations of interest:

- members of the committee 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
- five additional academic papers submitted with the application
- redacted peer review

- Genetic Alliance opinion

1. Consideration of application

1.1. The committee welcomed the advice of its specialist advisor, Professor Mary Porteous, who confirmed that the condition is as described in the papers.

1.2. The committee noted that the application is consistent with the Peer Review and Genetic Alliance opinion.

1.3. 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.

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

1.5. 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'.

1.6. The committee noted that the condition is inherited in an autosomal dominant pattern which means there is a 50% chance of having an affected child in each pregnancy, if either parent is a carrier of a relevant gene change.

1.7. The committee noted that individuals with Centronuclear Myopathy (DNM2-related) experience muscle weakness affecting the muscles of the hip and shoulder girdle, as well as those of the face and the muscles controlling eye movements. The condition is not generally non progressive but symptoms can get worse with age.

1.8. The committee noted that depending on the severity of muscle weakness complete independence in daily living may not be achieved. Further, complications from muscle weakness increases the risk of respiratory infections, orthopaedic deformity and scoliosis deformity which could require surgical intervention.

1.9. The committee noted that the onset of symptoms is usually in adolescence or adulthood and more rarely from birth

1.10. The committee noted that there is no curative treatment for the condition with symptoms only being treatable.

2. Decision

2.1. The committee considered that the condition is serious due to the impact on muscle strength, mobility and muscle pain and could affect independent living. Presently there is no treatment available other than symptomatic treatment.

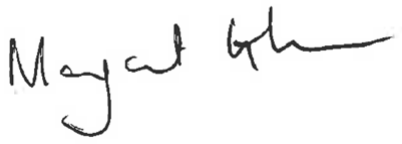
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious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

2.3. The committee agreed to authorise the testing of embryos for Centronuclear Myopathy, OMIM #160150.

3. Chair's signature

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

Signature



Name

Margaret Gilmore

Date

09 December 2016