Statutory Approvals Committee - minutes

Centre 0044 (The Centre for Reproductive Health & Genetic Health – PGD application for VICI Syndrome OMIM # 242840

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
- 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 recessive manner which means that there is a 25% chance of having an affected child in each pregnancy, if each parent is a carrier of a relevant gene change.

1.7. The committee noted that the condition is a rare congenital multisystem disorder characterised by agenesis of the corpus callosum, cataracts, pigmentary defects, progressive cardiomyopathy and variable immunodeficiency.

1.8. The committee noted that children with Vici syndrome are also profoundly delayed in the development of social and communication skills with many failing to achieve head control, roll over, sit independently, smile or speak. Available treatments only target symptoms associated with the condition and those affected typically die during childhood, most commonly following cardiorespiratory failure in the context of a respiratory tract infection and/or immunodefiency.

1.9. The committee noted that the condition is 100% penetrant and the onset of symptoms is from birth

1.10. The committee noted that there is no curative treatment for the condition.

2. Decision

2.1. The committee considered that the condition is serious due to the severity of its symptoms which are life limiting and the fact there is no cure.

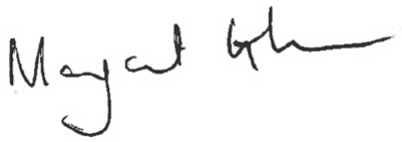
2.2. The committee had regard to its explanatory note and noted that on the basis of the information presented, given the condition's worst symptoms, it was satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious 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 Vici syndrome, OMIM #242840.

Chair's signature

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

Signature



Name

Margaret Gilmore

Date

09 December 2016