Statutory Approvals Committee – minutes

Centre 0119 (Birmingham Women's Hospital)

Pre-implantation Genetic Diagnosis (PGD) application for Isolated Growth Hormone Deficiency-type 1A (IGHD1A)

OMIM #262400

Thursday, 26 September 2019

HFEA, Spey Meeting Room, Level 2, 10 Spring Gardens, London, SW1A 2BU

Committee members	Margaret Gilmore (Chair) Anne Lampe Emma Cave Ruth Wilde	
Members of the Executive	Moya Berry Catherine Burwood	Committee Officer Licensing Manager
Specialist Adviser	Dr. Jenny Carmichael	
Legal Adviser	Tom Rider	FieldFisher LLP
Observers	Bernice Ash	Committee Officer

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:

- 9th 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 UK statement

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 Isolated Growth Hormone Deficiency-type 1A (IGHD1A) OMIM #262400 is consistent with the peer review.

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

1.4. The committee noted that the Genetic Alliance UK statement provided a perspective on the impact of the condition on patients, their families and carers.

1.5. 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.

1.6. 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 Isolated Growth Hormone Deficiency-type 1A (IGHD1A) OMIM #262400 is inherited in an autosomal recessive pattern, which means there is a 25% chance of an embryo being affected by the condition in each pregnancy if each parent has a relevant mutation.

1.8. The committee noted the penetrance of the condition is 100%.

1.9. Isolated Growth Hormone Deficiency-type 1A (IGHD1A) OMIM #262400 is caused by a lack of growth hormone, leading to severely reduced growth and unusually short stature evident from birth. Other symptoms include, mid-face hypoplasia, truncal obesity, delayed secondary dentition and high-pitched voice. Puberty may be delayed. Deficiencies in other pituitary hormones can occur and cause even more severely reduced growth and skeletal maturation, and prevent puberty, affecting fertility. The condition is associated with increased morbidity and the propensity to develop metabolic syndrome in later life with hyperlipidaemia, and hypertension increasing the risk of heart disease, stroke and type 2 diabetes.

1.10. There is no cure for this condition, Treatment involves daily growth hormone (GH) injections from diagnosis of the GH deficiency. Typically, patients respond well to initial therapy but often develop anti-GH antibodies leading to a loss of efficacy, making the condition difficult to treat.

1.11. The committee noted the executive's request to consider Isolated Growth Hormone Deficiency-type 1A (IGHD1A) OMIM #262400 for inclusion on the list of conditions approved for PGD. The committee agreed to consider the application on this basis.

1.12. The committee noted the peer reviewer also discussed other types of the condition which are characterised by growth failure, but without making recommendation that they should be considered for approval. These are Isolated Growth Hormone Deficiency1B OMIM # 612781, Isolated Growth Hormone Deficiency 2 (IGHD2) OMIM #173100, Isolated Growth Hormone Deficiency 3 (IGHD3) OMIM #307200, Isolated Growth Hormone Deficiency 4 (IGHD4) OMIM #618517 and Isolated Growth Hormone Deficiency 5 (IGHD5) OMIM #618016.

2. Decision

2.1. The committee considered that, in the worst-case scenario Isolated Growth Hormone Deficiency-type 1A (IGHD1A) OMIM #262400 is a rare condition that develops from birth and causes multiple impairments. The condition requires daily growth hormone injections from infancy but children often develop antibodies leading to a loss of efficacy of treatment. In adulthood, patients may develop metabolic syndrome. The committee noted the possible physical and psychological effects on those affected with the condition.

2.2. The committee considered the other conditions, Isolated Growth Hormone Deficiency1B OMIM # 612781, Isolated Growth Hormone Deficiency 2 (IGHD2) OMIM #173100, Isolated Growth Hormone Deficiency 3 (IGHD3) OMIM #307200, Isolated Growth Hormone Deficiency 4 (IGHD4) OMIM #618517 and Isolated Growth Hormone Deficiency 5 (IGHD5) OMIM #618016. and agreed that as all these conditions have a good response to growth hormone treatment it was not appropriate to consider them under this application.

2.3. The committee had regard to its explanatory note and confirmed that, on the basis of the information presented, it was satisfied that there is a particular risk that an embryo may have the abnormalities in question and that there is a significant risk, that a person with such an abnormality will, given the conditions' worst symptoms, have or develop a serious physical disability, a serious illness or any other serious medical condition.

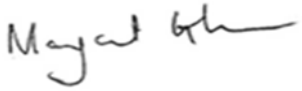
2.4. The committee was therefore satisfied that the following conditions meet the criteria for testing under paragraph 1ZA(1)(b) and (2) of Schedule 2 of the Act. The committee agreed to authorise testing for:

- Isolated Growth Hormone Deficiency-type 1A (IGHD1A) OMIM #262400

3. Chairs signature

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

Signature



Name
Margaret Gilmore

Date
28 October 2019