Freedom of Information Act 2000 disclosure log entry

Reference
19-20152

Date sent
23/08/2019

Subject
Application Response re 2010 Trial Using Triptorelin

Details of enquiry
Please can you send me the following information:

1) The inquiry from your research team based at the Gender Identity Development Service to the Medicines and Healthcare products Regulatory Agency on 14 April 2010 concerning the proposed trial using Triptorelin to treat children suffering from gender dysphoria.
2) The reply from the Medicines and Healthcare products Regulatory Agency to you on 15 April 2010 stating that this did not constitute a clinical trial.

Please note that you have confirmed the sending of this request and the receipt of a reply here:

We inquired with the MHRA regulatory body on 14 April 2010 which confirmed on 15 April that an evaluation of timing change (i.e. earlier) use of a drug (GnRH analogue, Triptorelin) routinely used within our clinical practice at 16 years plus, did not constitute a clinical trial of an investigational medicinal product and thus did not need MHRA authorisation. http://gids.nhs.uk/our-early-intervention-study

Response Sent
Your request for information, as detailed in your email below, has been considered in line with the requirements of the FOI Act 2000, and the copy correspondence requested is attached, and therefore now available to you.

Please note that the information provided under FOI is information held at the date on which the request was made. If you wish to discuss any of the above please contact me, quoting the reference details in the subject header of this email.

[redacted]

UCL Institute of Child Health and UCLH
6th Floor, 250 Euston Rd, Lon NW1 2PG

Tel [redacted]
Email: [redacted]

---------- Forwarded message ----------
From: Clinical Trial Helpline [redacted]
Date: Apr 15, 2010 4:42 PM
Subject: RE: Revised GID protocol - An evaluation of early pubertal suppression in a carefully selected

group of adolescents with Gender Identity Disorder
To: [redacted]

Dear [redacted]

Thank you for your email dated 14 April 2010.

I can confirm that your proposal is not a Clinical Trial of an Investigational Medicinal Product (IMP) as defined by the EU Directive 2001/20/EC. You therefore are not required to submit a Clinical Trial Authorisation (CTA) to the MHRA.

Please note that this e-mail is a normal form of communication for this advice by the MHRA and no letter will be sent out for this.

Kind regards

[redacted]

Clinical Trial Helpline
MHRA

From: [redacted]
Sent: 14 April 2010 09:51
To: Clinical Trial Helpline
Subject: Revised GID protocol - An evaluation of early pubertal suppression in a carefully selected group of adolescents with Gender Identity Disorder

Dear Sir/Madam,

We would be grateful for your advice on whether a study that we are proposing requires MHRA authorisation.

A copy of the study protocol is attached.

A small number of young people with gender identity disorder will be prescribed Triptorelin by injection in early-mid adolescence to 'pause' puberty. This will allow them to explore their feelings about their gender without the pressure of advancing puberty, until, at 16, they are able to make a

[redacted]

decision as to whether or not they wish to pursue gender reassignment therapy.

This study will be undertaken within the national Gender Identity Service based in London between the Tavistock and UCLH hospitals. Triptorelin is already used to induce a sex hormone-neutral environment in older adolescents (aged 16+) whilst they decide, as above, whether or not they wish to pursue gender reassignment.

In undertaking this study, we will be evaluating the benefits of this therapy in younger adolescents within the research framework of a prospective uncontrolled observational study. However this is not a trial of a novel medicinal compound per se, and this therapy is merely an extension downwards in age of a treatment we routinely use at age 16 years plus.

Our question is whether in setting up this study, for which we are going through formal research ethics application, we also need to apply for MHRA authorisation.

With many thanks in advance for your advice,

Best wishes,

[redacted]

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[redacted]

UCL Institute of Child Health and UCLH
6th Floor, 250 Euston Rd, Lon NW1 2PG

Tel [redacted] extension [redacted]
Email: [redacted]

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