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http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/CJD/fs/en
http://www.blood.co.uk/
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8) For Health Protection Agency media enquiries please contact the Agency's Centre for Infections Press Office on:

Kate Swan	020 8327 7097
Alexandra Baker	0208 327 7098
Louise Brown	020 8327 7080
George Fletcher	020 8327 6690

Last reviewed: 17 February 2009

別紙様式第４

医薬品　研究報告　調査報告書

識別番号・報告回数	F	第1報	報告日	第一報入手日	新医薬品等の区分	機構処理欄
			2009年03月04日	2009年02月18日	該当なし	

一般的名称	1. 乾燥濃縮人血液凝固第８因子（6343406） 2. ルリオクトコグアルファ（遺伝子組換え）（6343432） 3. 乾燥人血液凝固因子抗体迂回活性複合体（6343414）	研究報告の公表状況	http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1234859690542?p=1231252394302	公表国 イギリス
販売名（企業名）	1. ヘモフィルM（634340612）（Baxter） 2. リコネイト（634343201） 3. ファイバ（634341401） 4. ガンマガード（634342002） 5. プラズマプロティンフラクション（634342204			

研究報告の概要

（概要）：イギリスのおける血友病患者でのvCJDのリスクに関する報告

HPA（英国　Health Protection Agency）から、感染に対する規制が導入される以前に血漿分画製剤を投与された70歳代の血友病患者において、検死によりvCJD感染が報告された。他の死因や症状はなかったとHPAは報告している。

この血友病患者において vCJD 異常性プリオン蛋白質がどのように感染したかについての最終の評価はまだであるが、vCJD に対する安全性を確保する法案が導入された1999年以前、この患者が、1996年に血漿を提供し６カ月後にvCJDの症状を発現したドナーの血漿から生産された1バッチの第VIII因子製剤で治療されていたことは知られている。本報告は、vCJD異常性プリオン蛋白質が、初めて血友病患者において見いだされた、あるいは血漿分画製剤を使用された患者での最初の報告である。凝固因子製剤によるvCJの感染のリスクは、医師によって血友病患者へ伝えられており、2004年にはすでに1980から2001年の間に英国の血漿から生産された製剤で治療されていた血友病患者において、vCJD感染のリスクがあると言われていた。この新しい調査結果は、今まで理論的なリスクであったものが、リスクはまだ非常に小さいものであるが、血漿分画製剤で治療された患者にとって、実際のリスクがあることを示す。血液を通しての vCJD感染のリスクが最初に評価されていたときから、多くの予防措置が英国の血液の供給からリスクを最小にするために導入されている。英国の血漿が1999年から凝固因子製剤の製造のために使われておらず、合成された凝固因子製剤が患者に提供されている。

報告企業の意見	今後の対応
当該事象は、血漿分画製剤を投与された血友病患者で初めて報告されたものである。患者は、供血後にvCJDを発症したドナーから製造された血漿分画製剤を投与されていたことから、血漿分画製剤との関連を否定できないと考える。 なお、本報告で使用された製剤は、非加熱製剤の可能性が高いと考える。また、ヘモフィルMは承認を有しているが、本邦の市場には流通していない。リコネイトについても、販売を中止し本邦において、現在流通していない。ファイバ、ガンマガード、プラズマプロテインフラクション、ブミネートについては、当該報告と採血国も異なり、また、これまでにvCJD感染の報告もなく、感染のリスクは低いと考える。	今後も同様の情報収集に努める。

使用上の注意記載状況・その他参考事項等

[使用上の注意記載事項]

ヘモフィルM：記載なし

リコネイト：現在までに本剤の投与により変異型クロイツフェルト・ヤコブ病（vCJD）等が伝播したとの報告はない。しかしながら、本剤の添加物である人血清アルブミンの製造工程において異常プリオンを低減し得るとの報告があるものの、理論的なvCJD 等の伝播のリスクを完全には排除できないので、投与の際には患者への説明を十分行い、治療上の必要性を十分検討の上投与すること。

ファイバ、ガンマガード、プラズマプロテインフラクション、ブミネート：現在までに本剤の投与により変異型クロイツフェルト・ヤコブ病（vCJD）等が伝播したとの報告はない。しかしながら、製造工程において異常プリオンを低減し得るとの報告があるものの、理論的なvCJD 等の伝播のリスクを完全には排除できないので、投与の際には患者への説明を十分行い、治療上の必要性を十分検討の上投与すること。

別紙様式第４

医薬品　研究報告、調査報告書

識別番号・報告回数			報告日	第一報入手日	新医薬品等の区分	機構処理欄
一般的名称	4. 乾燥イオン交換樹脂処理人免疫グロブリン（6343420） 5. 加熱人血漿たん白（6343422） 6. 人血清アルブミン（6343410）		研究報告の公表状況		公表国	
販売名（企業名）	） 6. ブミネート（634341005）					

研究報告の概要	使用上の注意記載状況・その他参考事項等

報告企業の意見	今後の対応

Health Protection Agency

Protecting people
Preventing harm
Preparing for threats

vCJD abnormal prion protein found in a patient with haemophilia at post mortem

17 February 2009

Evidence of infection with the agent (abnormal prion protein) that causes variant Creutzfeldt-Jakob Disease (vCJD) has been found at post mortem in the spleen of a person with haemophilia.

The patient, who was over 70 years old, died of a condition unrelated to vCJD and had shown no symptoms of vCJD or any other neurological condition prior to his death. The vCJD abnormal prion protein was only identified during post mortem research tests.

The Health Protection Agency is working with the UK Haemophilia Centre Doctors Organisation to ensure all patients with bleeding disorders are made aware of this preliminary information which is being further investigated. This new finding will not change the way patients with haemophilia are cared for or treated.

A final view as to how vCJD abnormal prion protein was transmitted to this haemophilia patient has yet to be reached because investigations are continuing to determine the most likely route of transmission. It is known that the patient had been treated with several batches of UK sourced clotting factors before 1999, which is when measures to improve the safety of blood in relation to vCJD were introduced. The patient's treatment had included one batch of Factor VIII that was manufactured using plasma from a donor who went on to develop symptoms of vCJD six months after donating the plasma in 1996.

This is the first time that vCJD abnormal prion protein has been found in a patient with haemophilia, or any patient treated with plasma products. This new finding, however, does not change the public health vCJD 'at risk' status of patients with bleeding disorders.

Haemophilia patients have previously been informed by their doctors of their possible increased risk of exposure to vCJD via clotting factors. In 2004 all patients with bleeding disorders who had been treated with UK-sourced pooled plasma products between 1980 and 2001 were told that, owing to potential vCJD infectivity from these products they were to be classified as at-risk of vCJD for public health purposes.

Professor Mike Catchpole, Director of the Health Protection Agency's Centre for Infections, said:

"This new finding may indicate that what was until now a theoretical risk may be an actual risk to certain individuals who have received blood plasma products, although the risk could still be quite low. We recognise that this finding will be of concern for persons with haemophilia who will be awaiting the completion of the ongoing investigations and their interpretation.

The priority is to ensure that patients are informed of this development and have access to the latest information and specialist advice from their own haemophilia centre doctor as soon as possible.

"This finding does not change our understanding of the risk from vCJD for other people in any specific way. But it does reinforce the importance of the precautionary measures that have been taken over the years.

"Since the risk of vCJD transmission through blood was first considered, a number of precautionary measures have been introduced to minimise the risk from the UK blood supply. UK plasma has not been used for the manufacture of clotting factors since 1999 and synthetic clotting factors are provided for all patients for whom they are suitable."

Ends

Notes for editors

1) The post-mortem tests were carried out as part of a research study jointly coordinated by the UK Haemophilia Centre Doctors Organisation and the National CJD Surveillance Unit. The study was commissioned in 2001 and is ongoing.

2) The likelihood of a person who is infected with the vCJD abnormal prion protein going on to develop symptoms of the disease is uncertain and may depend on individual susceptibility. It is possible that infected individuals may never develop symptoms.

3) Haemophilia is a genetic blood condition in which an essential clotting factor is either partly or completely missing. This causes a person with haemophilia to bleed for longer than normal. Treatment for haemophilia is usually by replacing the missing clotting factor

(factor VIII) through regular injections which helps the blood to clot and minimises the likelihood of long term joint damage.

4) In 2004 all patients with bleeding disorders who had been treated with UK-sourced pooled plasma products (e.g. clotting factors for individuals with haemophilia) between 1980 and 2001 were told that, owing to potential vCJD infectivity from these products, they would be classified as at-risk of vCJD for public health purposes.

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