Безопасность препаратов плазмы – последние данные

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Современные меры по обеспечению безопасности препаратов плазмы

NAT – анализ нуклеиновых кислот. Высокоточный метод, позволяющий выявить единичные вирусные частицы

Меры по обеспечению безопасности донорской плазмы:

Отбор доноров

Анализ на наличие вирусных маркеров, в том числе, биотехнологический скрининг на наличие вирусных частиц (NAT)

Методы инактивации и удаления вирусов:

Обработка по методу С/Д

Термообработка

Нанофильтрация

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Вирусная безопасность: официальные рекомендации

Согласно Управлению по контролю за продуктами и лекарствами США, «ни препараты из плазмы, ни рекомбинантные препараты не содержат патогенных микроорганизмов» (FDA, 2003).

Из письма Управления по контролю за лекарственными препаратами и продуктами питания (FDA) США к производителям рекомбинантных факторов Bayer и Wyeth (2004) :

«Цитируемые материалы, содержащие заявления о большей безопасности и преимуществах Ваших препаратов, являются неверными или вводящими в заблуждение, потому что, насколько нам известно, это не было подтверждено реальными доказательствами или действительным клиническим опытом».

«FDA не известны какие-либо данные, подтверждающие, что Ваши продукты обладают лучшей вирусной безопасностью, чем какие-либо другие антигемофильные факторы»

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Прионная безопасность – последние данные (1)

Не используется плазма доноров, проживавших в Великобритании

▲

Изучаются этиология, патогенез, эпидемиология прионных заболеваний ⟶

Передача прионов ассоциирована большей частью с лейкоцитами!

Прионная безопасность – последние данные (2)

Валидационное исследование с искусственно зараженным материалом при стандартных технологических процессах (Svae et al., 2008)

Вывод: Необходимо 111 900 лет профилактического лечения при гемофилии А при условии, что все 11 600 пулов плазмы заражены прионами

Методы вирусной инактивации рекомбинантных препаратов

…3. Степень очистки – шесть валидизированных этапов очистки, включая два этапа вирусной инактивации

(Брошюра Когенэйт)

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Вирусы в клетках китайского хомячка

MVM

(Guide to microbiological control in pharmaceuticals and medical devices, Stephen P. Denyer, Rosamund M. Baird, 2-2007, CRC Press, p.100)

Ретровирусоподобные частицы

(J P Betts, *BMJ* 1998;316:1385)

Vesivirus 2117– поражение культуры клеток, проблемы с наличием препаратов

http://www.emea.europa.eu/humandocs/PDFs/EPAR/Cerezyme/51076609en.pdf

Вирусы считаются непатогенными для человека, но…

SV40: история

- 1955 – начало использования вакцины, полученной из культуры клеток обезьян
- 1960-е – выделен SV40
- 1970-е – показана возможная роль SV40 в возникновении некоторых опухолей
- 2000-е - вопрос по-прежнему открыт

1. Shah K, Nathanson N: Human exposure to SV40: Review and comment. Am J Epidemiol 103:1-12, 1976
2. Poulin DL, DeCaprio JA (2006). "Is there a role for SV40 in human cancer?". *J. Clin. Oncol.* **24** (26): 4356–65

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А также…

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Наступает эра зоонозов?

- SARS
- Птичий грипп
- Свиной грипп

Выводы

Культуры клеток животных, так же как и плазма здоровых доноров, содержат различные малопатогенные вирусы, роль которых неясна

Современные методы вирусной инактивации обеспечивают безопасность и плазматических, и рекомбинантных препаратов