

Wuhan company EV71 vaccine joint immunization informed consent

(6 month old inoculation of EV71, hepatitis B vaccine)

Dear parents and friends:

We sincerely invite you to pay attention to 6 month old or 8 month old children inoculated with enterovirus 71 vaccine (EV71 vaccine), and hepatitis B vaccine, leprosy vaccine, Japanese encephalitis vaccine, vaccine combined with immune vaccine safety and immunogenicity. The project by the Shandong provincial CDC, carried out in Shaanxi, Hunan, Shanxi, Shandong four provinces, the purpose is to evaluate the inactivated EV71 vaccine were immunogenic vaccine combined with immune and other non-inferiority, safety, provide a scientific basis for perfecting the immune strategy of china.

According to China's current immunization vaccination program, with 6 month old children to hepatitis B vaccination third serogroup A vaccine agent, first agents, 8 month old full vaccination needs of leprosy vaccine, live attenuated JE vaccine. According to China's vaccine specification, EV71 vaccine in more than 6 month old vaccinated first, at least 1 months interval dose second.

Process:

First, the doctor will inform you about the information that will be vaccinated. If you agree with this vaccination, we will know your baby's health after signing the informed consent.

According to the research group, a group of baby in 6 month old and third of hepatitis B vaccine inoculation and EV71 agent, and received second doses of the EV71 vaccine in 7 month old groups; two baby in 6 month old hepatitis B vaccination third agents; group three baby in 6 month old when inoculated with EV71 first agents, 7 month old agents with EV71 second. In the process, all the babies in each group were required to take 1 blood samples at 6 month old time before and at 8 month old, each time 2-3ml.

According to the randomization principle, your baby into a group:

1 2 3

The collection of blood samples will be operated by qualified professional medical staff. After the blood collection, please press the dry cotton ball in the blood collection part for 5 minutes to no bleeding. There may be transient pain, subcutaneous congestion, and other local reactions, which usually do not need special treatment. Blood samples were used to detect the level of hepatitis B and EV71 antibody, and the remnants of blood samples were destroyed immediately after the blood samples were detected. This test is free and will feed back the results to you in time.

In accordance with the unified requirements of vaccination, your baby should be vaccinated for 30 minutes. A doctor will provide a vaccination diary card and tell you to record / reflect the possible adverse reactions.

Related risk:

like all vaccines, vaccinations may cause local pain, induration, fever, headache, fatigue and occasional nausea and vomiting after vaccination. In general, no special treatment is needed, and it can be relieved by itself. Most people will have rapid allergic reaction, neurodropsy, urticaria and other serious reactions, if necessary, please contact the inoculation units in time

to deal with.

Benefit:

The vaccines used in this study were all qualified for the China food and drug testing institute, and the State Food and Drug Administration issued the products. The vaccine is a market sales/government procurement vaccine and is safe and effective for the human body. The whole vaccination of hepatitis B vaccine and EV71 vaccine can stimulate the body to produce immunity against hepatitis B virus and EV71 virus, prevent and resist hepatitis B and EV71 infection. You can contact your doctor at any time and get the proper guidance when you have a problem with the body during the vaccination.

Right:

Whether your baby is involved in this study is entirely out of your own mind. If you refuse to participate or withdraw from the midway, you will not affect any rights and interests you and your baby should get.

Confidentiality:

This study has been approved by the ethics committee. All the information we know, including personal privacy and blood test results, are strictly confidential and only be fed back to you. All relevant information will be kept tightly. The information will be summarized and analyzed anonymously, and the report does not contain any personal information.

Contact:

If you don't understand what problems or suggestions, please come out, we will try our best to help, you can also directly contact the local center for Disease Control and prevention: the relevant professional knowledge Advisory: control center telephone county / District disease prevention:

On ethical issues, please contact the provincial centers for Disease Control and prevention.

In order to thank you for your participation, we will also give you a small gift. Your participation will help the country to improve the appropriate immune procedures to protect more children and adults.

Thank you for your participation. Thank you for your cooperation.

Shandong Center for Disease Control and Prevention
County / District Center for Disease Control and Prevention
October 27, 2017

Signing of the informed consent form:

If you agree with your baby to participate in this project, please tick the following entries (entries have agreed to draw "√", do not agree with the items of painting "X"), and sign the name and date, thank you!

I have read / understand the above information and know the information needed to participate in the above survey

The questions that I care about are also explained by the investigators

My signature below shows that I agree with me to take part in the questionnaire

My signature below indicates that I agree with my child (by my representative) to participate in the questionnaire survey and blood specimen collection (including follow-up, investigation, blood specimen collection).

Guardian Name:

Name of the child:

Year month day

Implementation of the informed consent procedure statement:

I confirm that we have explained the nature and purpose of the project to the above.

I have answered all the questions that have been raised, and have witnessed the above signatures.

Person carrying out the informed consent procedure

Signature:

Year month day

Wuhan company EV71 vaccine joint immunization informed consent

(6 month old inoculation of EV71, MPSV-A vaccine)

Dear parents and friends:

We sincerely invite you to pay attention to 6 month old or 8 month old children inoculated with enterovirus 71 vaccine (EV71 vaccine), and hepatitis B vaccine, leprosy vaccine, Japanese encephalitis vaccine, vaccine combined with immune vaccine safety and immunogenicity. The project by the Shandong provincial CDC, carried out in Shaanxi, Hunan, Shanxi, Shandong four provinces, the purpose is to evaluate the inactivated EV71 vaccine were immunogenic vaccine combined with immune and other non-inferiority, safety, provide a scientific basis for perfecting the immune strategy of china.

According to China's current immunization vaccination program, with 6 month old children to hepatitis B vaccination third serogroup A vaccine agent, first agents, 8 month old full vaccination needs of leprosy vaccine, live attenuated JE vaccine. According to China's vaccine specification, EV71 vaccine in more than 6 month old vaccinated first, at least 1 months interval dose second.

Process:

First, the doctor will inform you about the information that will be vaccinated. If you agree with this vaccination, we will know your baby's health after signing the informed consent.

According to the research group, a group of children in the 6 month old and first EV71 were inoculated vaccine agent, 7 month old received second doses of the EV71 vaccine, 9 month old epidemic cerebrospinal meningitis vaccine second agents; group two baby respectively in the 6 month old 9 month old epidemic cerebrospinal meningitis vaccine every 1 agent; group three baby in 6 month old when inoculated with EV71 first, 7 month old when inoculated with EV71 second agent. In the process, all the babies in each group were required to take 1 blood samples at 6 month old time before and at 10 month old, each time 2-3ml.

According to the randomization principle, your baby into a group:

1 2 3

The collection of blood samples will be operated by qualified professional medical staff. After the blood collection, please press the dry cotton ball in the blood collection part for 5 minutes to no bleeding. There may be transient pain, subcutaneous congestion, and other local reactions, which usually do not need special treatment. Blood samples were used to detect the level of MPSV-A and EV71 antibody, and the remnants of blood samples were destroyed immediately after the blood samples were detected. This test is free and will feed back the results to you in time.

In accordance with the unified requirements of vaccination, your baby should be vaccinated for 30 minutes. A doctor will provide a vaccination diary card and tell you to record / reflect the possible adverse reactions.

Related risk:

like all vaccines, vaccinations may cause local pain, induration, fever, headache, fatigue and occasional nausea and vomiting after vaccination. In general, no special treatment is needed, and it can be relieved by itself. Most people will have rapid allergic reaction, neurodropsy,

urticaria and other serious reactions, if necessary, please contact the inoculation units in time to deal with.

Benefit:

The vaccines used in this study were all qualified for the China food and drug testing institute, and the State Food and Drug Administration issued the products. The vaccine is a market sales / government procurement vaccine and is safe and effective for the human body. The whole vaccination of hepatitis B vaccine and EV71 vaccine can stimulate the body to produce immunity against hepatitis B virus and EV71 virus, and prevent and resist hepatitis B and EV71 infection. You can contact your doctor at any time and get the proper guidance when you have a problem with the body during the vaccination.

Right:

Whether your baby is involved in this study is entirely out of your own mind. If you refuse to participate or withdraw from the midway, you will not affect any rights and interests you and your baby should get.

Confidentiality:

This study has been approved by the ethics committee. All the information we know, including personal privacy and blood test results, are strictly confidential and only be fed back to you. All relevant information will be kept tightly. The information will be summarized and analyzed anonymously, and the report does not contain any personal information.

Contact:

If you don't understand what problems or suggestions, please come out, we will try our best to help, you can also directly contact the local center for Disease Control and prevention: the relevant professional knowledge Advisory: control center telephone county/District disease prevention:

On ethical issues, please contact the provincial centers for Disease Control and prevention.

In order to thank you for your participation, we will also give you a small gift. Your participation will help the country to improve the appropriate immune procedures to protect more children and adults.

Thank you for your participation. Thank you for your cooperation.

Shandong Center for Disease Control and Prevention
County / District Center for Disease Control and Prevention
October 27, 2017

Signing of the informed consent form:

If you agree with your baby to participate in this project, please tick the following entries (entries have agreed to draw "√", do not agree with the items of painting "X"), and sign the name and date, thank you!

I have read / understand the above information and know the information needed to participate in the above survey

The questions that I care about are also explained by the investigators

My signature below shows that I agree with me to take part in the questionnaire
My signature below indicates that I agree with my child (by my representative) to participate in the questionnaire survey and blood specimen collection (including follow-up, investigation, blood specimen collection).

Guardian Name:

Name of the child:

Year month day

Implementation of the informed consent procedure statement:

I confirm that we have explained the nature and purpose of the project to the above.
I have answered all the questions that have been raised, and have witnessed the above signatures.

Person carrying out the informed consent procedure

Signature:

Year month day

Wuhan company EV71 vaccine joint immunization informed consent

(8 month old inoculation of EV71, MR vaccine)

Dear parents and friends:

We sincerely invite you to pay attention to 6 month old or 8 month old children inoculated with enterovirus 71 vaccine (EV71 vaccine), and hepatitis B vaccine, leprosy vaccine, Japanese encephalitis vaccine, vaccine combined with immune vaccine safety and immunogenicity. The project by the Shandong provincial CDC, carried out in Shaanxi, Hunan, Shanxi, Shandong four provinces, the purpose is to evaluate the inactivated EV71 vaccine were immunogenic vaccine combined with immune and other non-inferiority, safety, provide a scientific basis for perfecting the immune strategy of china.

According to China's current immunization vaccination program, with 6 month old children to hepatitis B vaccination third serogroup A vaccine agent, first agents, 8 month old full vaccination needs of leprosy vaccine, live attenuated JE vaccine. According to China's vaccine specification, EV71 vaccine in more than 6 month old vaccinated first, at least 1 months interval dose second.

Process:

First, the doctor will inform you about the information that will be vaccinated. If you agree with this vaccination, we will know your baby's health after signing the informed consent. L According to the research group, a group of baby in 8 month old and inoculated with EV71 and leprosy vaccine and vaccination with second doses of EV71 vaccine in 9 month old groups; two baby in 8 month old when inoculated with leprosy vaccine; group three baby in 8 month old when inoculated with EV71 first agents, 9 month old agents with EV71 second. In the process, all the babies in each group were required to take 1 blood samples at 8 month old time before and at 10 month old, each time 2-3ml.

According to the randomization principle, your baby into a group:

1 2 3

The collection of blood samples will be operated by qualified professional medical staff. After the blood collection, please press the dry cotton ball in the blood collection part for 5 minutes to no bleeding. There may be transient pain, subcutaneous congestion, and other local reactions, which usually do not need special treatment. Blood samples were used to detect the level of MR and EV71 antibody, and the remnants of blood samples were destroyed immediately after the blood samples were detected. This test is free and will feed back the results to you in time.

In accordance with the unified requirements of vaccination, your baby should be vaccinated for 30 minutes. A doctor will provide a vaccination diary card and tell you to record / reflect the possible adverse reactions.

Related risk:

like all vaccines, vaccinations may cause local pain, induration, fever, headache, fatigue and occasional nausea and vomiting after vaccination. In general, no special treatment is needed, and it can be relieved by itself. Most people will have rapid allergic reaction, neurodropsy, urticaria and other serious reactions, if necessary, please contact the inoculation units in time

to deal with.

Benefit:

The vaccines used in this study were all qualified for the China food and drug testing institute, and the State Food and Drug Administration issued the products. The vaccine is a market sales / government procurement vaccine and is safe and effective for the human body. The whole vaccination of hepatitis B vaccine and EV71 vaccine can stimulate the body to produce immunity against hepatitis B virus and EV71 virus, and prevent and resist hepatitis B and EV71 infection. You can contact your doctor at any time and get the proper guidance when you have a problem with the body during the vaccination.

Right:

Whether your baby is involved in this study is entirely out of your own mind. If you refuse to participate or withdraw from the midway, you will not affect any rights and interests you and your baby should get.

Confidentiality:

This study has been approved by the ethics committee. All the information we know, including personal privacy and blood test results, are strictly confidential and only be fed back to you. All relevant information will be kept tightly. The information will be summarized and analyzed anonymously, and the report does not contain any personal information.

Contact:

If you don't understand what problems or suggestions, please come out, we will try our best to help, you can also directly contact the local center for Disease Control and prevention: the relevant professional knowledge Advisory: control center telephone county / District disease prevention:

On ethical issues, please contact the provincial centers for Disease Control and prevention.

In order to thank you for your participation, we will also give you a small gift. Your participation will help the country to improve the appropriate immune procedures to protect more children and adults.

Thank you for your participation. Thank you for your cooperation.

Shandong Center for Disease Control and Prevention
County / District Center for Disease Control and Prevention
October 27, 2017

Signing of the informed consent form:

If you agree with your baby to participate in this project, please tick the following entries (entries have agreed to draw "√", do not agree with the items of painting "X"), and sign the name and date, thank you!

I have read / understand the above information and know the information needed to participate in the above survey

The questions that I care about are also explained by the investigators

My signature below shows that I agree with me to take part in the questionnaire

My signature below indicates that I agree with my child (by my representative) to participate in the questionnaire survey and blood specimen collection (including follow-up, investigation, blood specimen collection).

Guardian Name:

Name of the child:

Year month day

Implementation of the informed consent procedure statement:

I confirm that we have explained the nature and purpose of the project to the above.

I have answered all the questions that have been raised, and have witnessed the above signatures.

Person carrying out the informed consent procedure

Signature:

Year month day

Wuhan company EV71 vaccine joint immunization informed consent

(8 month old inoculation of EV71, JE-L vaccine)

Dear parents and friends:

We sincerely invite you to pay attention to 6 month old or 8 month old children inoculated with enterovirus 71 vaccine (EV71 vaccine), and hepatitis B vaccine, leprosy vaccine, Japanese encephalitis vaccine, vaccine combined with immune vaccine safety and immunogenicity. The project by the Shandong provincial CDC, carried out in Shaanxi, Hunan, Shanxi, Shandong four provinces, the purpose is to evaluate the inactivated EV71 vaccine were immunogenic vaccine combined with immune and other non-inferiority, safety, provide a scientific basis for perfecting the immune strategy of china.

According to China's current immunization vaccination program, with 6 month old children to hepatitis B vaccination third serogroup A vaccine agent, first agents, 8 month old full vaccination needs of leprosy vaccine, live attenuated JE vaccine. According to China's vaccine specification, EV71 vaccine in more than 6 month old vaccinated first, at least 1 months interval dose second.

Process:

According to the research group, a group of baby in 8 month old and inoculated with EV71 and first doses of JE vaccine, and vaccination with second doses of EV71 vaccine in 9 month old groups; two baby in 8 month old when the JE vaccine first agents; group three baby in 8 month old when inoculated with EV71 first agents, 9 month old agents with EV71 second. In the process, all the babies in each group were required to take 1 blood samples at 8 month old time before and at 10 month old, each time 2-3ml.

According to the randomization principle, your baby into a group:

1 2 3

The collection of blood samples will be operated by qualified professional medical staff. After the blood collection, please press the dry cotton ball in the blood collection part for 5 minutes to no bleeding. There may be transient pain, subcutaneous congestion, and other local reactions, which usually do not need special treatment. Blood samples were used to detect the level of JE-L and EV71 antibody, and the remnants of blood samples were destroyed immediately after the blood samples were detected. This test is free and will feed back the results to you in time.

In accordance with the unified requirements of vaccination, your baby should be vaccinated for 30 minutes. A doctor will provide a vaccination diary card and tell you to record / reflect the possible adverse reactions.

Related risk:

like all vaccines, vaccinations may cause local pain, induration, fever, headache, fatigue and occasional nausea and vomiting after vaccination. In general, no special treatment is needed, and it can be relieved by itself. Most people will have rapid allergic reaction, neurodropsy, urticaria and other serious reactions, if necessary, please contact the inoculation units in time to deal with.

Benefit:

The vaccines used in this study were all qualified for the China food and drug testing institute, and the State Food and Drug Administration issued the products. The vaccine is a market sales / government procurement vaccine and is safe and effective for the human body. The whole vaccination of hepatitis B vaccine and EV71 vaccine can stimulate the body to produce immunity against hepatitis B virus and EV71 virus, and prevent and resist hepatitis B and EV71 infection. You can contact your doctor at any time and get the proper guidance when you have a problem with the body during the vaccination.

Right:

Whether your baby is involved in this study is entirely out of your own mind. If you refuse to participate or withdraw from the midway, you will not affect any rights and interests you and your baby should get.

Confidentiality:

This study has been approved by the ethics committee. All the information we know, including personal privacy and blood test results, are strictly confidential and only be fed back to you. All relevant information will be kept tightly. The information will be summarized and analyzed anonymously, and the report does not contain any personal information.

Contact:

If you don't understand what problems or suggestions, please come out, we will try our best to help, you can also directly contact the local center for Disease Control and prevention: the relevant professional knowledge Advisory: control center telephone county / District disease prevention:

On ethical issues, please contact the provincial centers for Disease Control and prevention.

In order to thank you for your participation, we will also give you a small gift. Your participation will help the country to improve the appropriate immune procedures to protect more children and adults.

Thank you for your participation. Thank you for your cooperation.

Shandong Center for Disease Control and Prevention
County / District Center for Disease Control and Prevention
October 27, 2017

Signing of the informed consent form:

If you agree with your baby to participate in this project, please tick the following entries (entries have agreed to draw "√", do not agree with the items of painting "X"), and sign the name and date, thank you!

I have read / understand the above information and know the information needed to participate in the above survey

The questions that I care about are also explained by the investigators

My signature below shows that I agree with me to take part in the questionnaire

My signature below indicates that I agree with my child (by my representative) to participate in the questionnaire survey and blood specimen collection (including follow-up, investigation,

blood specimen collection).

Guardian Name:

Name of the child:

Year month day

Implementation of the informed consent procedure statement:

I confirm that we have explained the nature and purpose of the project to the above.

I have answered all the questions that have been raised, and have witnessed the above signatures.

Person carrying out the informed consent procedure

Signature:

Year month day