

Evaluation of GlaxoSmithKline's MMR Vaccine

What vaccines are being evaluated?

GlaxoSmithKline manufactures a combination Mumps, Measles, Rubella vaccine, which is licensed in 90 countries, including Canada, Europe and Australia. Over 175 million doses have been distributed.

This study is being done to evaluate GSK's MMR vaccine in the US for licensure by the FDA. It will be compared to the only existing US-licensed MMR vaccine (MMR-II®) which is manufactured by Merck & Co.

Why is this study being done?

GSK would like to bring their MMR vaccine to the US market. An additional licensed MMRV vaccine should increase the availability of combination vaccines, and decrease cost due to competition.

What does the study entail?

Children will receive all of the recommended vaccines at their 12-month routine physical appointment. Of each four children participating, three will receive GSK's MMR, and one will receive Merck's MMR. They will also receive a routine Prevnar® Booster and Hepatitis A vaccine.

Families will complete a diary after immunization. Protection levels to all vaccines given will be tested with a 1 tsp blood sample before and six weeks after vaccination. This second blood draw is your only additional visit to the Pediatric Center. At your child's routine 18-month physical, they will receive their second Hepatitis A vaccine.

What are the risks?

The vaccines may cause fever or fussiness and a reaction at the injection site (pain, redness, or swelling). Blood drawing can be uncomfortable and sometimes a bruise results. The nurse can use a numbing cream to lessen the pain.

Why participate?

There is a need for additional manufacturers of MMR vaccine in the US. A second licensed option for this routine childhood vaccine can assure additional supply in case of an unforeseen shortage, and may reduce the vaccine price due to competition.

When blood is drawn in the office for the study, an additional amount can be obtained for a CBC/Lead level, which will be ordered routinely at the 12-month physical. This will save you a trip to a local laboratory for venipuncture.

There is no charge to participate and the vaccines are given free of charge. Your family will be given a \$40 Target gift card after each of the visits to thank you for your time and effort.

Where can I find more information? Nancy Wymer RN at 301-662-2051

http://thepedcenter.com/ed_info/VaccineInfo.aspx