A Case Control Study of the Effectiveness of Q/LAIV Versus Inactivated Influenza Vaccine and No Vaccine in Subjects 2-17 Years of Age

Sponsor Protocol Number: MA-VA-MEDI3250-1116

Application Number: Not applicable

Investigational Product: FluMist® Quadrivalent/Fluenz Tetra - a quadrivalent live attenuated influenza vaccine (Q/LAIV)

Sponsor: MedImmune, LLC, a wholly owned subsidiary of AstraZeneca
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3900 Paramount Parkway
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Protocol, Date: Original Protocol, 23Apr2013
Administrative Change 1, 28Aug 2015 (applicable to the United Kingdom only)

Study MI- MA-VA-MEDI3250-1116

Administrative Change 1 to Protocol

Rationale for Administrative Change

The purpose of this administrative change is to extend study MI-MA-VA-MEDI3250-1116 to the United Kingdom to allow enrollment of children 2 to 7 years of age seeking care for febrile acute respiratory illness in the emergency department of hospital clinics. The 2 to 7 years' age group is targeted for universal vaccination by the England influenza immunization programme in influenza season 2015-2016.

Summary of Administrative Changes

The following changes were made:

- Section 4.2 (Subject Selection and Withdrawal) - updated to provide details of the informed consent process to be implemented in the United Kingdom for this young age group (2 to 7 years)
- Section 4.2.1 (Inclusion Criteria) - Inclusion Criteria 1 and 2 amended to specify that eligible subjects in the UK will be 2 to 7 years of age seeking care in the emergency department of hospital clinics. All other inclusion criteria in Section 4.2.1 of the original protocol are applicable

Note: Changes to wording in the sections below are shown as bolded, stricken text.

Protocol Section Changed: Section 4.2 (Subject Selection and Withdrawal)

Enrollees will be community-dwelling children and adolescents 2 to 17 years of age seeking care in an outpatient setting for febrile acute respiratory illness.

The investigator (physician) or qualified designee will discuss the study with the subject/legal representative of a subject who is considered a potential candidate for the study and provide the legal representative with the study-specific informed consent form and informed assent form approved by the Institutional Review Board (IRB). The investigator or designee will address any questions and/or concerns that the legal representative may have and, if there is continued interest, will secure written informed consent and written informed assent for participation in the study. Written informed consent and any locally required authorization (eg, Health Insurance Portability and Accountability Act [HIPAA]

authorization) and written informed assent will be obtained prior to conducting any protocol-specific procedures.

See Section 10.3 for additional details concerning informed consent.

Now Reads

Enrollees will be ~~community-dwelling~~ children ~~and adolescents~~ 2 to ~~17~~ **7** years of age seeking care in ~~an outpatient setting~~ **the emergency department of hospital clinics** for febrile acute respiratory illness.

The investigator (physician) or qualified designee will discuss the study with the **parent/legal guardian** ~~subject/legal representative~~ of a subject who is considered a potential candidate for the study and provide **them** ~~the legal representative~~ with the study-specific **information sheet and** informed consent form ~~and informed assent form~~ approved by the **Research Ethics Committee (REC)**. ~~Institutional Review Board (IRB).~~ The investigator or designee will address any questions and/or concerns that the **parent/legal guardian** ~~legal representative~~ may have and, if there is continued interest, will secure written informed consent ~~and written informed assent~~ for participation in the study. Written informed consent ~~and any locally required authorization (eg, Health Insurance Portability and Accountability Act [HIPAA] authorization) and written informed assent~~ will be obtained prior to conducting any protocol-specific procedures.

See Section 10.3 for additional details concerning informed consent.

Protocol Section Changed: Section 4.3.1 (Inclusion Criteria)

1. Community-dwelling individual resides in the counties or zip codes surrounding the participating study centers
2. Age 2 through 17 years at the time of enrollment

Now Reads

1. ~~Community-dwelling~~ Individual resides in the counties ~~or zip codes~~ surrounding the participating study centers **in the United Kingdom**
2. Age 2 through ~~17~~ **7** years at the time of enrollment