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LEGACY01: ASSESSMENT AND FOLLOW-UP

In 1 collection

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ABSTRACT

This protocol details assessment and follow-up in an experimental medicine study of seasonal influenza vaccination responses in Lymph nodE single-cell Genomics in AnCestrY (LEGACY01).

ATTACHMENTS

602-1266.docx

GUIDELINES

ASSESSMENT AND FOLLOW-UP

Participants who may be eligible will be identified through access to the National Institute for Health Research (NIHR) Imperial Clinical Research Facility (CRF) healthy volunteer database, and through advertising the study across multiple outlets including in the community, in the workplace and online. Written information about the study will be made available on request. Interested potential participants will be invited for a face-to-face screening visit.

STUDY ASSESSMENT SCHEDULE

Participants will be followed up according to the study schedule in Table 1. Participants will attend a screening visit at the study site, and they will be asked to provide proof of identity at the visit. Written informed consent will be obtained from participants before undergoing study procedures. The visits in the study assessment schedule are a screening visit (V1), an enrolment visit at which the first FNA will be performed (V2), a vaccination visit (V3), a follow-up visit at which the second FNA will be performed (V4) and a final follow-up visit (V5). In addition, participants will be

contacted by telephone (V2a) a few days after the first FNA at V2.

PROCEDURES DURING THE SCREENING PERIOD

Informed consent

Participants will be given written information about the study, the sampling procedures, the vaccine and the data collection and sharing. Those who wish to proceed will be asked to sign a witnessed consent form before undergoing screening investigations. A copy will be provided to the participant, and one kept in the study file according to local SOPs.

Eligibility

Eligibility will be assessed by means of demographics, medical history, medications, physical examination and laboratory investigations. Screening examination will include clinical observations (blood pressure, temperature and pulse), height and weight, inspection of the FNA sites (skin and an assessment of lymph nodes). Symptom directed examination will be at discretion of the physician. During the study, participants should not take any aspirin or medication that may increase risk of bleeding 7 days before each procedure. Enrolment of participants who usually take these medications for any reason will be at the discretion of the investigator.

Clinical laboratory investigations

Tests to be conducted at screening are in Table 1 and its footnotes. Individuals with laboratory abnormalities at screening considered clinically significant by the investigator and likely to interfere with the conduct of the study will not be eligible for enrolment.

PROCEDURES AT ENROLMENT AND FOLLOW UP

Fine needle aspiration

Participants will undergo fine needle aspiration of suitable axillary lymph nodes at enrolment, and again after receiving immunisation. The process for sampling is described in Appendix 2.

Injection

Intramuscular injection of seasonal influenza vaccine into the deltoid muscle of participants' choice will be according to standard clinical practice. The arm injected will be recorded. Prior to receiving the injection, the participant will have vital signs measured. A temperature of 37.8 °C or above would prevent injection on the day. Introduction of new concomitant medications such as immunosuppressive medications, or new acute illness may prevent injection on the day at discretion of the investigator. Participants will remain at the study site for at least 00:30:00 after injection, for safety reasons.

COVID-19

Participants will be asked about COVID-19 symptoms at every visit. Presence of highly likely COVID-19 symptoms in the opinion of the investigator will trigger a PCR or lateral flow test (which can be self-taken) in accordance with NHS guidance. The visit will be delayed until the result is known. A negative response will allow the visit to continue per protocol.
A positive response will delay the visit until the NHS stipulated period of isolation is complete.

Receiving an authorised COVID-19 vaccine

It is anticipated that volunteers entering the study will already have received a full course of COVID-19 vaccination as defined by the Green Book chapter 14a. If they have not done so, volunteers are encouraged to receive a full course of COVID-19 vaccination at least 28 days before enrolling onto the study. Volunteers who enrol and subsequently become eligible for an authorised COVID-19 vaccine booster through standard NHS care can receive the vaccine during the study. A gap of at least 28 days either side of an FNA is preferred but where there is clinical imperative a shorter gap is acceptable. Where a COVID-19 vaccine is scheduled near to an FNA, the FNA should occur before the vaccination where possible.

PROCEDURES FOR ASSESSING SAFETY

Seasonal influenza vaccine is a widely used licensed product with a well described post-licensure safety profile. Detailed information on safety data available for aQIV is available in section 2 study design and in Appendix 1. aQIV is subject to additional monitoring and healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard

Fine needle aspiration is a standard and well-tolerated clinical technique. Safety assessments on the study will be limited to assessing the safety and tolerability of study procedures purely in order to safeguard the wellbeing of participants, in accordance with the experimental medicine framework for the study. There are no safety-related objectives of the study.

PROCEDURES FOR ASSESSING IMMUNE RESPONSES

Whole blood and lymph node samples will be collected to assess cellular immunity and humoral immunity and DNA extracted for genomic analysis such as HLA typing. Whole blood will be collected at Visits 2 and 3-5. Lymph node samples will be collected at Visits 2 and 4. Pax gene tubes for assessing the RNA transcriptome will be collected at Visits 3 and 4.

INCIDENTAL FINDINGS

An incidental finding is one that has potential health or reproductive importance, which is discovered unexpectedly but is unrelated to the purpose or aims of the study e.g., an abnormal laboratory safety test result. Local site (NIHR Imperial CRF) procedures will be followed. Depending on the nature of the finding, the subject might have to be withdrawn or vaccination or sampling discontinued, and his/her GP informed.

LOSS TO FOLLOW-UP

Participants who do not attend scheduled visits will be contacted according to local standard procedures which includes contacting through telephone and NHS text. Every reasonable attempt will be made to maintain contact with participants during their participation in the study.

STUDY CLOSURE

The study will be closed when all participants have completed their final follow-up visit and assessments are completed including those to determine resolution of any adverse events and the data recorded and locked.