ISRCTN60691705 https://doi.org/10.1186/ISRCTN60691705

A pilot study to determine the feasibility and acceptability of the recruitment and follow-up procedures planned for a large scale study (phase IIb) of a novel influenza vaccine

Submission date
27/09/2016

Recruitment status
No longer recruiting

Registration date
11/10/2016

Overall study status
Completed

Last Edited
23/04/2021

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The flu (or seasonal Influenza) can have a big impact on health and global economics. The elderly are one group that are more likely to suffer from the flu. Vaccines are an affordable and effective method to protect people from flu infections. Studies have shown that vaccines that are able to create an immune response to the flu by increasing the number of protective T-cells (a type of white blood cell) can help make symptoms less severe and last for a shorter time. The main study (INVICTUS), that this initial study will inform, will be testing the effectiveness of a new type of flu vaccine. To ensure the success, quality and reliability of INVICTUS and the results it produces, a smaller study is needed to provide information about how the main study should be designed and how to recruit participants. This study is split into two phases. The first phase of the study aims to find out how acceptable the recruitment procedure is to participants, and the second phase of the study aim to find out about how acceptable the follow up processes in the study would be to participants.

Who can participate?
Adults aged 65 years and over who are eligible to receive a seasonal flu jab. In phase 2 of the study, participants must not have already had their flu jab.

What does the study involve?
Phase 1: Participants receive a confirmation letter of their appointment, and the participant information sheet (PIS) for RIVET Phase 1 and INVICTUS in the post before the appointment. At the appointment, the nurse takes consent and then runs through a mock version of the INVICTUS initial procedures. At the end, participants are asked to take part in a focus group about their experiences.
Phase 2: Participants receive the details of their appointment, the PIS for RIVET Phase 2 and INVICTUS in the post. Immediately after receiving their flu vaccine (that they would have had anyway) the follow up process begins. All participants are asked to complete a diary for one week after their initial appointment. This is collected online or in paper form according to the

participant's choice. From November 1st, or the beginning of flu season as determined by Public Health England, whichever is earliest, the participants are contacted every day, by email or text, to ask if they have had an influenza-like illness (ILI). They are also given a weekly diary card on which they can tick daily if they have experienced any ILI symptoms and return this by post if they would prefer. When they have an ILI episode, they start recording data either electronically or in paper form in a Flu Symptoms Diary. The study team contact the participants once a month to check how they are, see if they have had an ILI episode and monitor how they are managing with the follow up. Participants are followed until 30th April 2017 or the end of the flu season as determined by Public Health England, whichever is later. A safety review is conducted via telephone between 24 – 72 hours after their vaccination. Further attempts, if needed, take place between days 7 – 9 after their vaccination. At the end of the follow-up period participants are interviewed about their experiences.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved for participants taking part in this study.

Where is the study run from?
Nuffield Department of Primary Care Health Sciences (UK)

When is study starting and how long is it expected to run for?
October 2016 to October 2017

Who is funding the study?
Vaccitech (UK)

Who is the main contact?
Mrs Sarah Tearne

Contact information

Type(s)
Public

Contact name
Mrs Sarah Tearne

Contact details
Department of Primary Care Health Sciences
Radcliffe Primary Care
The Radcliffe Observatory Quarter
Woodstock Road
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United Kingdom
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Additional identifiers

Protocol serial number
CB/RIVET/0017

Study information

Scientific Title
RIVET: Re-inventing Influenza Vaccine Efficacy Trials

Acronym
RIVET

Study objectives
The aim of this study (RIVET) is to assess the feasibility and acceptability of the trial recruitment and follow-up processes of INVICTUS*.

*INVICTUS is a planned trial investigating the efficacy of a new flu vaccine. Influenza vaccine trials (like INVICTUS) can only be conducted at the start of each flu vaccine season (October each year) and if a trial is slow to recruit, part of the study will have to be deferred to the following year, and so this study aims to test and optimise the research team's interactions with volunteers to provide the best preparation for the INVICTUS study planned for October 2017.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Proportionate review sub-committee of the South East Scotland Research Ethics Committee 01, 09/09/2016, ref: 16/SS/0160

Study design
Phase 1: Observational pilot cross sectional study
Phase 2: Observational pilot cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Influenza vaccinations

Interventions
Phase 1:
Potential participants will be recruited through appropriate charities and local advertisements. The aim is to recruit 6 participants in total. Participants will be asked to contact the study team if they are interested in taking part. The research team will collect the participants contact details, including their address, book them an appointment to see a nurse at a GP practice and confirm the appointment via a confirmation letter that will be posted with the Participant Information Sheet's (PIS) for Phase 1 of RIVET and for INVICTUS.

At the baseline appointment, a research nurse will first take informed consent for participation in RIVET Phase 1. Once consent has been gained the research nurse will then run through a mock version of the INVICTUS baseline procedures. This will include assessing eligibility, going through

the INVICTUS consent procedure and running through all other procedures that would take place in the main trial however it will not include delivery of any flu vaccine. Each of these appointments will be timed. The additional time it will take to administer the two flu vaccines in INVICTUS will be calculated and added on to the observed timing of the recruitment visit. The aim here is to try and imitate what will happen in the main trial as closely as possible i.e. the data collection and randomisation process.

Consent will be sought from participants to allow us to collect baseline information through direct data entry (DDE) to replicate the planned procedures for the INVICTUS recruitment visit. At the end of this consultation the participants will be asked to take part in a focus group about their experiences.

Phase 2:
Potential participants will be recruited through appropriate charities and local advertisements and asked to contact the study team if they would like to take part. The aim is to recruit between 20 - 40 participants in total, these will be different participants to those participants in Phase 1. At the time of contacting the study team, the potential participant must not have received their annual influenza vaccination. The research team will collect the participants contact details, including their address, book them a baseline appointment. Confirmation of the appointment will be made via a letter posted along with the PIS for RIVET Phase 2 and the INVICTUS Trial.

At the baseline appointment the researcher will take informed consent. Following this, participants will be informed about the follow up procedures and provided with an oral thermometer, tape measure and their follow up diaries. If they opt to use the electronic follow up system then this will be set up at this visit. Participants must inform the study team when they are booked in to receive their influenza vaccination so that the study team can anticipate when their follow up period will start.

Immediately after receiving their influenza vaccination the follow up process will begin. All participants will complete a diary for one week after their baseline appointment to record any perceived adverse events (AE). This will be collected online or in paper form according to the participant's choice. From the first of November, or the beginning of influenza season as determined by Public Health England through national influenza surveillance, whichever is earliest, the participants will be contacted every day to ask if they have had an influenza-like illness (ILI). This contact will be made via email or text message. They will additionally be given a weekly diary card on which they can tick daily if they have experienced any ILI symptoms and return this by post if they would prefer. They will be asked to start recording data in a Flu Symptoms Diary when they do have an ILI episode. This will be collected electronically or in paper form according to the participant's choice. Any paper diaries will be posted back to the study team once complete.
Additionally once a month the participants will be telephoned by a member of the study team to check how they are, see if they have had an ILI episode and monitor how they are managing with the follow up process. Participants will be followed until 30th April of that season or the end of the influenza season as determined by Public Health England through national influenza surveillance, whichever is later.

A safety review will be conducted via telephone between 24 – 72 hours after their vaccination. If contact cannot be made after three attempts, further attempts will take place between days 7 – 9 after their vaccination.

At the end of the follow-up period all participants will be contacted by the study team to conduct a final qualitative interview about their experiences.

Intervention Type
Other

Primary outcome(s)
Phase 1:
1. Acceptability to participants of baseline procedures is assessed through a focus group at the end of the baseline visit with all those who took part in phase 1
2. Average length of time of baseline procedure calculated through calculation of the mean time of all baseline visits
3. Acceptability to study staff of baseline procedures is assessed through interviews at the end of all baseline visits
4. Data entry errors will be counted to provide an overall total at the end of the baseline visit. In addition frequency of errors will be calculated for each data point

Key secondary outcome(s))
1. Acceptability to participants of follow up methods is assessed through interviews at the end of the follow up period with all phase 2 participants
2. Completeness of diary entry will be assessed through reviewing all missing data. Frequency of missing data across the whole cohort will be calculated for each data point where data was missed. This will take place at the end of the follow up period.

Completion date
01/10/2017

Eligibility

Key inclusion criteria
1. Willing and has capacity to provide written informed consent for participation in the study and to comply with all study requirements (in the Investigator's opinion)
2. Male or female adults, aged 65 years or above
3. Eligible to receive seasonal influenza vaccine

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria

1. Ongoing terminal illness with a life expectancy of <6 months
2. Any other significant disease, which, in the opinion of the Investigators, would put at risk their ability to comply with the study procedures
3. Have already received the annual seasonal influenza vaccine (Phase 2 participants only)

Date of first enrolment
11/10/2016

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nuffield Department of Primary Care Health Sciences
Radcliffe Primary Care Building
Radcliffe Observatory Quarter
Woodstock Road
Oxford
United Kingdom
OX2 6GG

Sponsor information

Organisation
Vaccitech

ROR
https://ror.org/02m8mqx79

Funder(s)

Funder type
Industry

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated are not going to be stored in a publically available repository. They are going to be stored on OpenClinica (password protected access to study team personnel only).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.1	21/09/2016	11/10/2016	No	Yes
Participant information sheet	version V1.1	21/09/2016	11/10/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes