

SIVE II: an evaluation of the seasonal influenza vaccine using routine data sources

Submission date 17/11/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 17/11/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/03/2021	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Globally, it is estimated that seasonal influenza is responsible for five million cases of severe illness and 500,000 deaths per year, in particular older adults aged 65 and over and people with underlying diseases such as asthma. National influenza vaccination strategies using primary care represent a potentially important approach to reduce both influenza-related illness and death, hence the considerable investment in this preventive approach in many parts of the world. In Scotland new policy interventions are imminent and will result in the broader coverage of the vaccine, e.g. a new type of influenza vaccine (live attenuated influenza vaccine) is being introduced this year to all children (between 2 and 17 years). However, the evaluation of changes to immunisation programmes can be problematic given that randomised controlled trials of the vaccine are impractical and also viewed as unethical by some sections of the medical community. These policy changes therefore typically go unevaluated, making it difficult to inform ongoing policy deliberations. Building on our substantial track-record of evaluating vaccine programmes using linked healthcare electronic record-derived information, we will conduct an evaluation of the live attenuated influenza vaccine.

Who can participate?

Rather than recruiting participants, the SIVE II project instead uses data collected from routinely available datasets.

What does the study involve?

Rather than recruiting participants, the SIVE II project instead uses data collected from routinely available datasets.

What are the possible benefits and risks of participating?

The observational study design being used to assess the effectiveness of influenza vaccine does not influence the care that is provided or the people who receive it. Therefore there are minimal risks and no direct benefits to patients.

Where is the study run from?

Centre for Population Health Sciences (UK).

When is the study starting and how long is it expected to run for?
The study will run from October 2014 to April 2017.

Who is funding the study?
NIHR Health Technology Assessment - HTA (UK).

Who is the main contact?
Dr Colin Simpson
c.simpson@ed.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Colin Simpson

ORCID ID
<https://orcid.org/0000-0002-5194-8083>

Contact details
Centre for Population Health Sciences
Medical School
Teviot
Edinburgh
United Kingdom
EH8 9AG
+44 131 651 4151
c.simpson@ed.ac.uk

Additional identifiers

Protocol serial number
HTA 13/34/14

Study information

Scientific Title
Seasonal Influenza Vaccination Effectiveness II (SIVE II): use of a large national primary care and laboratory-linked dataset to evaluate live attenuated and trivalent inactivated influenza vaccination effectiveness

Acronym
SIVE II

Study objectives

To provide early estimates of the uptake and effectiveness of LAIV administered to children (from 2013) and explore indirect effects of LAIV on the general population. Our secondary aim is to evaluate the effectiveness of seasonal TIV amongst older people (65 years and older) and those with asthma under 65.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee West Midlands - Edgbaston, 22/01/2015, ref: 15/WM/0035

Primary study design

Observational

Study design

Observational longitudinal cohort study with nested-case control study

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Influenza

Interventions

16 influenza vaccine programmes implemented in Scotland will be evaluated for effectiveness.

Intervention Type

Biological/Vaccine

Phase

Not Applicable

Primary outcome(s)

Influenza positivity from virological swab data in vaccinated and unvaccinated patients stratified by at-risk populations, age, sex and socioeconomic status

Key secondary outcome(s)

1. Consultation for influenza-related morbidity (e.g., influenza, pneumonia, chronic obstructive pulmonary disease [COPD] and cardiac-related consultations) and issue of antiviral therapy from general practice data in vaccinated and unvaccinated patients stratified by at-risk populations, age, sex and socio-economic status
2. Mortality and influenza-related serious morbidity (e.g., influenza, pneumonia, COPD and cardiac-related death and hospitalisation from SMR01 records) in vaccinated and unvaccinated patients stratified by at-risk populations, age, sex and socioeconomic status

Completion date

01/04/2017

Eligibility

Key inclusion criteria

All (anonymised) patient data will be collected

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

All

Sex

All

Total final enrolment

1250000

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/10/2014

Date of final enrolment

01/04/2017

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre

Centre for Population Health Sciences

Edinburgh

United Kingdom

EH8 9AG

Sponsor information**Organisation**

Academic and Clinical Centre Office for Research and Development (ACCORD) (UK)

ROR

<https://ror.org/01x6s1m65>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK) (HTA 13/34/14)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	12/03/2021	Yes	No
Protocol article	protocol	28/02/2017	23/10/2020	Yes	No
HRA research summary			28/06/2023	No	No