

Influenza vaccine in nursing homes - why doesn't it work?

Submission date
26/07/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
05/10/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
14/09/2009

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
SL&M Research Ethics Committee 04/045

Study information

Scientific Title

Study objectives

Primary Objectives: To determine whether assessing antibody response to the influenza vaccine, and administering a booster vaccination if the antibody response is inadequate, is more effective in reducing hospitalisation and death rates than current standard practice.

Secondary Objectives: To estimate the overall antibody response rate to the influenza vaccine in the trial population; To investigate whether non-response to the influenza vaccine is associated with HLA type, psychiatric diagnosis, Cornell score or MMSE score; To investigate whether assessing antibody response to the influenza vaccine, and administering a booster vaccination if the antibody response is inadequate, increases antibody response rates relative to current standard practice; To investigate what baseline factors predict clinical response (hospitalisation and death rates) and antibody response across intervention groups (including Cornell score, MMSE score, psychiatric diagnosis, and HI titres); To investigate whether Cornell score, MMSE score and HLA type differentially predict clinical response (hospitalisation and death rates) and antibody response to the intervention versus control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from South London And Maudsley Research Ethics Committee (ref: 04/045)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Influenza

Interventions

Randomised into immediate assay of 21-day haemagglutination inhibition (HAI) antibody response to flu vaccine, and administration of booster if antibody response inadequate, as compared to treatment as usual.

Intervention Type

Biological/Vaccine

Phase

Not Specified

Primary outcome(s)

Hospitalisation (Yes/No) between randomisation and 30th April 2005.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/07/2005

Eligibility

Key inclusion criteria

All consenting/assenting individuals in care homes with nursing care who receive their primary care from Lambeth and Southwark primary care trusts (PCTs), who would ordinarily receive the influenza vaccine are eligible for inclusion in the trial.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

If an individual has had a reaction to the initial flu vaccine or if the flu vaccine is contra-indicated in that individual, then they will be excluded from the trial.

Date of first enrolment

01/08/2004

Date of final enrolment

31/07/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Consultant Psychiatrist and Hon. Senior Lecturer

London

United Kingdom

SE13 6LW

Sponsor information

Organisation

South London And Maudsley NHS Trust (UK)

ROR

<https://ror.org/015803449>

Funder(s)**Funder type**

Charity

Funder Name

Charitable Foundation of Guy's and St. Thomas' (UK) (R031166)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2007		Yes	No