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

Submission date	Recruitment status	[_] Prospectively registered
26/07/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2009	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Fiona Gaughran

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2004

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

Age group
Senior

Sex
Both

Target number of participants
277

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
England

United Kingdom

Study participating centre
Consultant Psychiatrist and Hon. Senior Lecturer
London
United Kingdom
SE13 6LW

Sponsor information

Organisation
South London And Maudsley NHS Trust (UK)

Sponsor details
Dr. Gill Dale
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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