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Cost benefit evaluation of routine influenza immunisation in subjects 65-74 years of age

Submission date	Recruitment status	[_] Prospectively registered
25/04/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 97/20/06

Study information

Scientific Title

Cost benefit evaluation of routine influenza immunisation in subjects 65-74 years of age

Study objectives
We have already shown in Merseyside that <50% of high risk elderly patients admitted to hospital with acute medical illnesses have received influenza vaccination. As a result of this study 8 Practices have been recruited as a PCII. In each of these Practices a Data Manager funded by the Health Authority is already accruing data on influenza-type illnesses as well as epidemiological data. These Practices are the obvious sites for this study representing a typical elderly population seen in inner cities. North Mersey Community Trust are already training Nurse Immunisers and we are confident with this manpower we could vaccinate the anticipated numbers required during a 4-6 week period. We believe that the applying group have the necessary experience and expertise to identify suitable subjects in the Practices, manage a complex immunisation programme, coordinate the necessary end point measures and analyse the resultant data. We have the necessary links with the Pharmacy Department of a teaching hospital familiar with randomisation and drug distribution for various clinical trials. We have the support of the 8 Practices involved in PCII and that of the Director of Public Health for Liverpool. We have access to University computing and library facilities necessary for the data handling and systematic review respectively.

Please note that, as of 11/05/2009, the anticipated end date has been updated from 31/08/2001 to 31/08/2002.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Infection and infestations: Influenza

Interventions
Please note that, as of 14 January 2008, the anticipated end date of this trail has been updated from 31 August 2001 to 31 August 2002.

Interventions:
1. Pneumococcal and influenza
2. Pneumococcal and placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1.1 Hospital admission with or without respiratory illness
1.2 GP consultation for respiratory and non-respiratory disease
1.3 Self- reported patient illness and over the counter medication
1.4 Quality of Life measures at 3, 6, 9 and 12 months post vaccination.
2. To determine the cost effectiveness of the vaccination.
3. To determine whether factors such as age, sex, co-morbidity and social class affects, 3.1 entry into the trial, 3.2 the receipt or otherwise of the influenza vaccination outside the clinical trial, 3.3 cost effectiveness.

Key secondary outcome(s)
Not provided at time of registration.

Completion date
31/08/2002

Eligibility

Key inclusion criteria
65-74 year olds

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
729

Key exclusion criteria
Aged over 75 years

Date of first enrolment
01/09/1999

Date of final enrolment
31/08/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Health Sciences
Reading
United Kingdom
RG1 5AQ

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	01/02/2003		Yes	No