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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/04/2003		Protocol		
Registration date 25/04/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 10/07/2019	Condition category Infections and Infestations	Individual participant data		
10/01/2017				

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

- 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.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/09/1999

Completion date

31/08/2002

Eligibility

Key inclusion criteria

65-74 year olds

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Not provided at time of registration.

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

England

United Kingdom

Study participating centre Institute of Health Sciences

Reading United Kingdom RG1 5AQ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

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	01/02/2003		Yes	No