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

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

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

## Type(s)

Scientific

#### Contact name

Dr Margot Gosney

#### Contact details

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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.

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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

Αll

#### 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