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Time of day and influenza vaccination study

Submission date 19/09/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/11/2012	**Overall study status** Completed	
Last Edited 05/05/2016	**Condition category** Other	

Plain English summary of protocol

Background and study aims
It is predicted that by 2020 approximately 1 in 5 of the UK population will be aged 65 or over and that by 2050 this could rise to 1 in 2.5. This increase in life expectancy has not been accompanied by an increase in healthy life expectancy; thus, there is a considerable drive to improve the health of older adults. It has long been recognised that older adults are more at risk of both bacterial and viral infections, prompting the introduction of the annual vaccination programme against influenza for adults aged over 65 years. However, the age-related decline in immune function (immunosenescence) reduces the ability of an older individual to mount a successful vaccination response. With age, the quantity (titre) and quality (affinity) of antibody produced in response to vaccination is reduced. Influenza vaccination of young adults provides 65% - 80% protection against illness whereas vaccination of older adults gives only 30-50% protection. A number of studies have sought to use behavioural interventions, such as an acute aerobic or eccentric weights protocol to improve response to vaccination, but recent observational research has revealed that the timing of vaccination administration may also affect immune response. This study aims to determine whether the time of day (morning vs afternoon) affects antibody response to influenza vaccination. Further, other related factors at the time of vaccination will also be measured as these factors may have an effect upon subsequent antibody response.

Who can participate?
The study involves recruiting over 65 year old males and females from the various surgeries participating in the West Midlands.

What does the study involve?
The participants are divided into two groups (morning vs afternoon vaccination). The study involves having a blood sample prior to annual influenza vaccination, filling out a questionnaire pack and returning for a follow up blood sample 4 weeks later. Anthropometric measurements (height, weight, waist-hip ratio) are also taken. The results of the tests from the two groups are compared.

What are the possible benefits and risks of participating?
Participation in this study helps us to find out whether a simple change in the time of vaccination

can help older adults have an improved immune response to vaccination and help protect against influenza. This knowledge could have a big impact upon patient care and medical practice. The only known risk within this study is bruising associated with blood being taken.

Where is the study run from?
The study is being carried out by the School of Sport and Exercise Sciences at the University of Birmingham. However, the participant attends their local GP surgery to have blood samples taken and their influenza vaccination given.

When is the study starting and how long is it expected to run for?
October 2011 to September 2014

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Anna Phillips
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Contact information

Type(s)
Scientific

Contact name
Dr Anna Phillips

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Type(s)
Scientific

Contact name
Mr Mark Drayson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RG_11-053

Study information

Scientific Title
Time of vaccination and other factors, and response to the annual influenza vaccine in older adults: a cluster-randomised trial

Study objectives
Our proposed study aims to confirm that a simple manipulation of the timing of vaccination will improve the immune response against influenza vaccination in older adults. This will yield an intervention that is easy to implement within the NHS, at little or no added cost. This is an observational study comparing antibody responses to influenza vaccination. Participants are cluster randomised according to their surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Birmingham Research Ethics Committee, 04/07/2011, ref: 11/WM/0161

Study design
Cluster randomised study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
This study involves aspects of ageing related to the immune response following vaccination

Interventions
The 2 groups (morning vs afternoon vaccination) will be compared. Antibody titres, cytokine levels, sex steroids (cortisol, DHEA, testosterone etc) will be measured at baseline to determine what factors at the time of vaccination may related to antibody response at follow up (4 weeks post vaccine)

Intervention Type
Biological/Vaccine

Primary outcome measure
Antibody response

Secondary outcome measures
1. Cytokine levels
2. Sex steroids
3. Psychosocial factors

Overall study start date
01/10/2011

Completion date
01/10/2014

Eligibility

Key inclusion criteria
Available to attend surgery for morning (9-11am) or afternoon (3-5pm) vaccination and blood samples, and a fasted morning blood sample one month later.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
No current condition such as cancer, diabetes, chronic fatigue which can affect response to vaccination. No acute infection e.g. a cold. No adverse reactions to blood sampling e.g. fainting.

Date of first enrolment
01/10/2011

Date of final enrolment
10/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
West Midlands CRN
United Kingdom
B15 2SQ

Study participating centre
North Staffordshire CCG
United Kingdom
ST5 1QG

Study participating centre
South Staffordshire CCG
United Kingdom
B78 3HF

Study participating centre
Telford & Wreaking CCG
United Kingdom
TF7 4BF

Study participating centre
Wolverhampton CCG
United Kingdom
WV10 9RU

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
c/o Brendan Laverty
Research and Commercial Services
Institute of Research and Development
Birmingham Research Park
Edgbaston
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United Kingdom
B15 2SQ

Sponsor type
University/education

Website
http://www.birmingham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council - Lifelong Health and Wellbeing Initiative (UK) ref: G1001390

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/05/2016		Yes	No