ISRCTN17197293 https://doi.org/10.1186/ISRCTN17197293

Molecular point-of-care 'test and treat' for influenza (FluPOC)

Submission date
06/11/2017

Recruitment status
No longer recruiting

Registration date
13/11/2017

Overall study status
Ongoing

Last Edited
18/05/2021

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Influenza causes thousands of people to become unwell and be admitted to hospital every year. There is a vaccine available to prevent influenza but not everybody receives it and some of those who do still catch influenza and become unwell. There are antiviral drugs available to treat influenza but they are not used as often as they should be. This is because patients admitted to hospital with influenza are not always tested for it and when they are, the standard test takes 24-48 hours to give a result. Recent studies have shown that antiviral drugs are very helpful in unwell patients admitted to hospital with influenza and so we must find a way to improve the numbers of patients who are diagnosed with influenza and treated with antivirals. There is a new test which is very accurate, gives results within one hour and can be used at the bedside as soon as patients come into hospital. By using this test in patients admitted to hospital it may improve the number of cases of influenza diagnosed and increases the number given antivirals. This study will evaluate the impact of a routine molecular point-of-care ‘test and treat’ strategy for influenza in adults hospitalised with acute respiratory illness.

Who can participate?
Patients aged 18 and older who have come in the emergency department for respiratory illness.

What does the study involve?
Participants are randomly allocated to one of two groups. One group has a nose and throat swab taken and the new test performed as soon as they come into hospital and the results given to the doctors and the patient. Patients with a positive test for influenza are offered antiviral medicines in accordance with UK guidelines. Those in the second group are managed in the standard way where doctors decide whether or not to send a test to the laboratory and then whether to offer antiviral medicines. The two groups are compared to see if having the new rapid test made any difference to their care or outcome.

What are the possible benefits and risks of participating?
Patients in the group with the new test may benefit from having their results much sooner than normal. Patents in the control group are not expected to benefit directly from being in the

study. The risks of respiratory tract sampling and additional blood tests being taken are minimal and where occurring are likely to be mild. No additional adverse events related to POCT for respiratory viruses are anticipated.

Where is the study run from?
1. Southampton General Hospital (UK)
2. Royal Hampshire County Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2015 to May 2026

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Tristan Clark (Scientific)
t.w.clark@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Tristan Clark

Contact details
University of Southampton and University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)2381208410
t.w.clark@soton.ac.uk

Additional identifiers

EudraCT/CTIS number
N/A

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35478

Study information

Scientific Title
Pragmatic, multicentre, randomised controlled trial evaluating a routine molecular Point-of-Care ‘test-and-treat’ strategy for influenza in adults hospitalised with acute respiratory illness: FluPOC

Acronym
FluPOC

Study objectives
A routine molecular Point-of-Care 'test and treat' strategy for influenza improves the care of adults hospitalised with acute respiratory illness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee (REC): South Central - Hampshire A Research Ethics Committee, 07/09/2017, ref: 17/SC/0368

Study design
Multicentre; Randomised; Interventional; Design type: Diagnosis, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Infection

Interventions
Current:
This study is a pragmatic, multi-centre, randomised controlled trial in adults with ARI admitted to University Hospital Southampton NHS Foundation Trust or Hampshire Hospitals Foundation NHS Trust, during influenza season.

Previous:
This study is a pragmatic, single-centre, randomised controlled trial in adults with ARI admitted to University Hospital Southampton NHS Foundation Trust, during influenza season.

840 patients are recruited over three influenza seasons and randomised (1:1) to receive either POCT using the FilmArray Respiratory Panel, or routine clinical care. Clinical and infection control teams are informed of the results in real time and where influenza is detected patients are offered NAI treatment immediately, in accordance with national guidelines. Those allocated to standard clinical care have a swab taken for later analysis to allow assessment of missed diagnoses. The outcomes assessment is done by retrospective case note analysis. The outcome measures include the proportion of influenza-positive patients detected and appropriately treated with NAIs, isolation facility use, antibiotic use, length of hospital stay, complications and mortality.

Intervention Type
Other

Primary outcome measure
Difference in the proportion of influenza positive patients treated appropriately with neuraminidase inhibitors (NAI) within 5 days of admission.

Secondary outcome measures
1. Proportion of cases of influenza identified
2. Proportion of cases of all respiratory viruses detected
3. Proportion of all NAI use occurring in influenza positive patients
4. Proportion of all NAI use occurring in influenza negative patients
5. Time from admission to NAI commencement in hours
6. Duration of NAI use in influenza positive patients, days and doses
7. Duration of NAI use in influenza negative patients, days and doses
8. Proportion of patients treated with antibiotics
9. Proportion of patients treated with single doses or brief courses (<48 hours) of antibiotics
10. Duration of antibiotic use in days
11. Proportion of patients isolated in a side room
12. Duration of isolation facility use
13. Proportion of influenza cases correctly isolated
14. Time from admission to isolation of influenza positive cases
15. Time from admission to de-isolation of influenza negative cases
16. Duration of hospitalisation in days
17. Time to clinical stability* in days
18. Time on supplementary oxygen in days
19. Proportion of patients with ICU or HDU admission
20. Duration of ICU or HDU stay in days
21. Proportion re-presenting to hospital within 30 days
22. Proportion readmitted to hospital within 30 days
23. In hospital, 30 and 60 day mortality
24. Turn-around time for viral testing

All outcomes are measured for the duration of hospitalisation or up to 30 days (whichever is shortest) unless specified otherwise and include medication (antibiotics and NAIs) that patients are discharged home with.

*Defined as: temperature ≤37.8C, respiratory rate ≤24 breaths per minute, heart rate ≤100 beats per minute, oxygen saturation ≥90% without the use of supplementary oxygen, systolic blood pressure ≥90 and normal mental status mmHg for at least 24 hours.

Overall study start date
01/10/2015

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Is a patient in the ED* or AMU at University Hospital Southampton NHS Foundation Trust (UHS) or [added 01/05/2019]: Hampshire Hospitals Foundation NHS Trust
2. Aged ≥18 years old
3. Has acute respiratory illness**
4. Duration of respiratory illness less than 10 days prior to hospitalisation
5. Can be recruited to the study within 16 hours of presentation

*For patients in ED a decision will have already been made that the patient will be admitted.
**An episode of acute respiratory illness is defined as an acute pulmonary illness (including pneumonia, bronchitis and influenza-like illness) or an acute exacerbation of a chronic respiratory illness (including exacerbation of COPD, asthma or bronchiectasis). For the study, acute respiratory illness as a provisional, working, differential or confirmed diagnosis must be made by a treating clinician.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 840; UK Sample Size: 840

Total final enrolment
613

Key exclusion criteria
1. Not fulfilling all the inclusion criteria
2. A purely palliative approach being taken by the treating clinicians
3. Previously included in this study and re-presenting within the last 30 days after hospital discharge
4. Declines nasal / pharyngeal swabbing
5. Consent declined or consultee consent declined

6. Concurrent, prior or subsequent enrolment in an observational study is not necessarily an exclusion criterion; this is at the discretion of the chief investigator and will be assessed on a case-by-case basis.

Date of first enrolment
01/12/2017

Date of final enrolment
17/05/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton General Hospital
University of Southampton and University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal Hampshire County Hospital
Hampshire Hospitals Foundation NHS Trust
Romsey Road
Winchester
United Kingdom
S022 5DG

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

Sponsor details
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton

England
United Kingdom
SO16 6YD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Plans to publish protocol.

Intention to publish date
01/05/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/12/2019	20/12/2019	Yes	No
Results article		01/04/2021	18/05/2021	Yes	No
HRA research summary			28/06/2023	No	No