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Covid-SMART: Optimising lateral flow testing for NHS staff release from quarantine and return from isolation

Submission date
25/01/2022

Recruitment status
No longer recruiting

Registration date
26/01/2022

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The problem addressed by this research is the lack of evidence for policymakers on how to balance the risks from Covid-19 directly with the indirect risks posed by key worker staff being absent after close contact with Covid-19 cases, or after having just recovered from infection with the virus - particularly with the Omicron variant. Recent NHS staff testing policies try to balance these risks, however, there is a need to know whether nose-only swabbing is sufficient for daily testing of contacts to release them back to work from quarantine. There is also a need to know whether 2 consecutive days of negative lateral flow tests from day 5 after exposure is sufficient to allow staff to return from work after they have recovered from infection. The potential additional risk mitigation of using two types of lateral flow tests is also understudied. In addition, there is a need to understand whether people who still test positive with lateral flow tests at day 10 after exposure can still be infectious.
The aim of this research is to maximise patient safety by balancing the risks from Covid-19 directly with those posed by key worker absence due to Covid-19.

Who can participate?
Any NHS staff using the Covid-19 staff testing facilities for contacts or cases at Liverpool University Hospitals NHS Foundation Trust can participate. All participants must be fully vaccinated.

What does the study involve?
Participants will be required to perform self-tests for COVID-19 for up to 10 days.

What are the potential benefits and risks of participating?
Participants will have additional Covid-safety assurance that they are likely to reduce the risk of transmitting the Covid virus to their patients and colleagues by taking part in this study with additional testing. Some may also perceive a benefit of contributing to policy-relevant evidence that is urgently needed. There are no known risks from participation, beyond the inconvenience of taking extra tests.

When is the study starting and how long is it expected to run for?
January 2022 to March 2022

Who is funding the study?
The UK Health Security Agency.

Who is the main contact?
Professor Iain Buchan, buchan@liverpool.ac.uk

Study website
https://www.dropbox.com/s/hna8rusxf64d2h5/SMART_Release_Return.pdf

Contact information

Type(s)
Principal Investigator

Contact name
Prof Iain Buchan

ORCID ID
https://orcid.org/0000-0003-3392-1650

Contact details
Institute of Population Health
University of Liverpool
F206, Waterhouse Building
1-5 Brownlow Street
Liverpool
United Kingdom
L69 3GL
+44 7802853367
buchan@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
311842

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UoL001685, IRAS 311842

Study information

Scientific Title
Covid-SMART release & return: urgent study of dynamic quarantine and isolation with alternative lateral flow devices and regimens

Acronym
Covid-SMART Release & Return

Study objectives
Research questions addressed by the study:
1. Does the addition of dual swabbing and use of two different manufacturer's devices at the same time add substantial value (in timely case detection) over a single device?
2. Does nose only swabbing detect Omicron infection as early as nose plus throat swabbing for lateral flow test (LFT)?
3. Is two consecutive days of negative (dual) LFT results a reliable indicator that an Omicron case will not subsequently revert to (validated) LFT positive/shedding within the same course of infection?
4. Will NHS staff cases take up the offer of an accelerated return to work given serial negative LFTs when their employer strongly encourages/organises participation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Liverpool Central University Research Ethics Committee, ref: 11002

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Workplace

Study type(s)
Diagnostic

Participant information sheet
https://www.dropbox.com/s/oehj3v31ov5anz1/SMART_RR_Participant_Information_V6.docx

Health condition(s) or problem(s) studied
Covid-19. Urgent study of dynamic quarantine and isolation with alternative lateral flow devices and regimens for NHS staff

Interventions
Urgent pilot service evaluation with randomised order of swabbing - nose/throat using Innova Lateral Flow Device (LFD) and nose only using Orient Gene LFD and internally controlled

comparison of single vs dual Lateral Flow Test (LFT) results. Observational study of serial dual LFT vs PCR Ct. Quantitative and qualitative (participant and employer survey) observational study of uptake and staffing impacts.

In concert with NERVTAG Virology Cell, a sample of Day 5 PCR swabs will be sent for viral culture.

Uninfected contact participant pathway:
1. Household member of NHS worker is notified they are Covid positive, so their NHS contact starts quarantine and notifies their employer.
2. Employer has adopted SMART Release & Return testing schedule as their local standard policy and directs the staff member to a booking website for the scheme, which provides and information sheet, consent process and directions to the unit/site.
3. Participant receives a 10-day pack of daily dual LFT + 2 PCR home test kits, and if they have not had a positive Covid test in the past 90 days they take a swab for quick turnaround (binary) PCR.
4. Participant receives PCR negative result on Day 0 and returns to work on Day 1 with DCT.
5. Innova (nose/throat) and either Orient Gene (nose only) lateral flow devices are used each morning (or pre-shift) before breakfast in randomised order for 10 days – an information sheet in the pack directs the participant day by day. Either LFD turning positive is an overall positive result.
6. On day 1 the participant also takes a home PCR swab (randomised order with the two LFTs) and returns it by post to Pillar 2 / other (ringfenced) Q-RT-PCR capacity, and the result is not used for any purpose other than research.
7. A second Q-RT-PCR swab is taken on day 5.
8. Exit questionnaire gathers participant experiences.

Asymptomatic infected contact participant pathway:
1. Household member of NHS worker is notified they are Covid positive, so their NHS contact starts quarantine and notifies their employer.
2. Employer has adopted SMART Release & Return testing schedule as their local standard policy and directs the staff member to a booking website for the scheme, and directs them to the standard testing/reception site.
3. Consented participant takes quick turnaround (binary) PCR test to return to work from quarantine on DCT and receives a 10-day pack of daily dual LFT + 2 PCR home test kits.
4. Participant receives PCR positive result on Day 0 and stays at home.
5. Innova (nose/throat) and Orient Gene (nose only) lateral flow devices are used each morning before breakfast in randomised order – an information sheet in the pack directs the participant day-by-day.
6. On day 1 the participant also takes a home PCR swab (randomised order with the two LFTs) and returns it by post to Pillar 2 / other (ringfenced) Q-RT-PCR capacity, and the result is not used for any purpose other than research.
7. Second Q-RT-PCR swab is taken on day 5. (Participant is selected to be in the viral culture sample of 30 cases – and their swab in viral transport medium is collected from their home).
8. If day 5 and 6 dual LFT results (4 tests) are negative the participant may return to work.
9. Daily dual LFT testing continues until day 10.
10. If still testing LFT positive at day 10 the participant is advised to call and arrange a RT-Q-PCR swab in viral transport medium for culture.
11. Exit questionnaire gathering participant experiences.

New case referred to the study
1. NHS worker is notified they are Covid positive and notifies their employer.
2. Employer has adopted SMART Release & Return testing schedule as their local standard policy

and directs the staff member to a booking website for the scheme, and directs them to the standard testing/reception site.
3. Consented participant receives a 10-day pack of daily dual LFT + 2 PCR home test kits.
4. Innova (nose/throat) and Orient Gene (nose only) lateral flow devices are used each morning before breakfast in randomised order – an information sheet in the pack directs the participant day-by-day.
5. On day 1 the participant also takes a home PCR swab (randomised order with the two LFTs) and returns it by post to Pillar 2 / other (ringfenced) Q-RT-PCR capacity, and the result is not used for any purpose other than research.
6. Second Q-RT-PCR swab is taken on day 5.
7. If day 5 and 6 dual LFT results (4 tests) are negative the participant may return to work.
8. Daily dual LFT testing continues until day 10.
9. If still testing LFT positive at day 10 the participant is advised to call and arrange a RT-Q-PCR swab in viral transport medium for culture.
10. Exit questionnaire gathering participant experiences.

Intervention Type
Other

Primary outcome measure
Covid case detection measured by dual swabbing of two different manufacturers lateral flow devices at the same time daily for up to 10 days

Secondary outcome measures
The earliest day of detection of Omicron infection measured using nose only swabbing lateral flow device Orient Gene

Overall study start date
04/01/2022

Completion date
31/03/2022

Eligibility

Key inclusion criteria
NHS staff working at Liverpool University Hospital Foundation Trust (LUHFT) sites who are fully vaccinated

Participant type(s)
Health professional

Age group
Mixed

Sex
Both

Target number of participants
2,000

Total final enrolment
1176

Key exclusion criteria
LUHFT staff that are not fully vaccinated

Date of first enrolment
31/01/2022

Date of final enrolment
11/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool University Hospital
Liverpool University Hospitals NHS Foundation Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
University of Liverpool

Sponsor details
Clinical Directorate
4th Floor Thompson Yates Building
Faculty of Health and Life Sciences
Liverpool
England
United Kingdom
L69 3GB
+44 7717863747
sponsor@liverpool.ac.uk

Sponsor type
University/education

Website
https://www.liverpool.ac.uk

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
Department of Health and Social Care

Alternative Name(s)
Department of Health & Social Care, DH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 24/04/2023:
Planned publication in high impact peer-reviewed journal following timely reporting to the UK Health Security Agency Testing Initiatives Evaluation Board

Previous publication and dissemination plan:
Planned publication in high impact peer-reviewed journal

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 21/05/2024:
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (GitHub): https://github.com/iain-buchan/cipha/blob/master/SMART_RR_Anonymised_Data.zip
The type of data stored: Anonymised, individual-level participant data on lateral flow test results

Dates of availability: Anytime
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: Fully anonymised – no feasible deductive disclosure

Previous IPD sharing plan:
The datasets generated during and analysed during the current study will be stored in a non-publically available repository: https://www.cipha.nhs.uk.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.9	24/01/2022	26/01/2022	No	No
Funder report results		05/09/2022	24/04/2023	No	No
Protocol file	version 4.7	26/07/2022	24/04/2023	No	No
Statistical Analysis Plan	version 4.7	26/07/2022	24/04/2023	No	No
Dataset		20/05/2024	21/05/2024	No	No
Participant information sheet		30/12/2023	21/05/2024	No	Yes
Results article		11/11/2024	20/11/2024	Yes	No