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Feasibility and clinical impact of rapid respiratory virus testing in a real-world setting

Submission date
29/11/2021

Recruitment status
No longer recruiting

Registration date
01/12/2021

Overall study status
Completed

Last Edited
18/11/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Influenza (the flu) and other viruses that have similar symptoms make many people sick every year. Some people get sick enough that they need to go to hospital. There are different treatments for influenza or other illnesses that have the same symptoms. Testing for influenza and other viruses tell the doctor how to treat them. Without these results, doctors must make decisions without knowing the cause of the illness. Newer quicker and easier to use tests (rapid NAT) can help doctors make their decisions faster, but they cost more. We must prove that these tests improve doctors' decisions. Studies have shown that rapid NAT may help doctors order the right medications and decrease the time someone needs to be in hospital. These other studies have mostly been done in an "artificial" study setting and may not be true in the real world. This study aims to see if these tests will improve patient care when ordered and tested by the people who would in the real world.

Who can participate?
Patients seen at one of the two study hospitals by a doctor who orders a respiratory virus test for their care

What does the study involve?
Samples taken for testing will be collected as per normal. The laboratory decides who gets the rapid test or just the standard test.

What are the possible benefits and risks of participating?
Results from tests for respiratory viruses (e.g. influenza) may be quicker than normal. The test results may guide the doctor to more appropriate and precise care. There is minimal risk to participants.

Where is the study run from?
Alberta Precision Laboratories (Canada)

When is the study starting and how long is it expected to run for?
September 2019 to June 2020

Who is funding the study?
Alberta Precision Laboratories (Canada)

Who is the main contact?
Dr Byron Berenger
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A pragmatic randomized controlled trial of rapid on-site influenza and respiratory syncytial virus PCR testing in pediatric and adult populations

Study objectives
1. A turnaround time (TAT) of 2 hours in 90% of cases is achievable by testing at hospital laboratories in Alberta.
2. Patients tested with a rapid test have a shorter length of hospital stay and improved utilization of other health care resources compared to a non-rapid test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2019, University of Calgary Conjoint Health Research Ethics Board (2500 University Drive NW, Calgary, AB, Canada; +1 (0)403 220 2297; chreb@ucalgary.ca), ref: REB19-2047

Study design
Two-centre parallel randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Influenza and respiratory syncytial virus

Interventions
Patients with a respiratory viral testing order are randomized to testing at either a central accredited laboratory with a respiratory pathogen panel nucleic acid test (standard arm) or with a rapid polymerase chain reaction test at an on-site accredited laboratory (rapid on-site test [ROST] arm) followed by standard of care testing. Randomization is done based on the day of receipt of the specimen in the hospital laboratory. Patients and clinicians are blinded to assignment.

Intervention Type
Other

Primary outcome(s)
1. Turnaround time for the rapid NAT or standard of care test, as measured from the time of collection of the sample to the verification of the result. Time of collection submitted by the collector and recorded in the laboratory information system (LIS). Time of result is when reported by the laboratory in the LIS. Times will be retrieved from the LIS at the end of the study.
2. Pediatric site (site 1) - Duration of hospital stay for patients tested for respiratory viruses, defined as the time from ER admission to hospital discharge or hospital admission to hospital discharge if ER admission time is not available. Patients seen only in ER will not be included in this endpoint. This is recorded in the clinical information system (CIS) and will be retrieved from there.
3. Adult/pediatric site (site 2) – a prescription of oseltamivir recorded in the CIS during the encounter. Data will be retrieved from the CIS.

Key secondary outcome(s))
All secondary outcome measures are recorded in the clinical information system as a part of routine care and will be retrieved from there at the end of the study:
1. A prescription of oseltamivir ordered during the encounter for site 1
2. Number of oseltamivir doses administered during the encounter
3. Time from the patient’s encounter start time to receipt of their first oseltamivir dose (if oseltamivir given)

4. A chest x-ray ordered*
5. Number of ancillary laboratory tests ordered*
6. A prescription of bacterial antimicrobial agents ordered*
7. Duration of emergency department stay if not admitted to hospital determined by the time of admission to discharge

*Orders for chest-x-rays, ancillary tests, antimicrobial agents (#3-6) will be included if they are ordered from the time of the respiratory virus NAT order to 24 h after the respiratory pathogen panel is resulted (standard test performed in standard arm and intervention arm after rapid onsite testing).

Completion date
16/06/2020

Eligibility

Key inclusion criteria
All patients with a respiratory virus nucleic acid test ordered by a physician at one of the two study hospitals

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
1090

Key exclusion criteria
Patients without a respiratory virus nucleic acid test ordered by a physician at one of the two study hospitals

Date of first enrolment
06/01/2020

Date of final enrolment
14/03/2020

Locations

Countries of recruitment
Canada

Study participating centre
Peter Lougheed Hospital
3500 26 Ave NE
Calgary
Canada
T1Y 6J4

Study participating centre
Alberta Children's Hospital
28 Oki Dr NW
Calgary
Canada
T3B 6A8

Sponsor information

Organisation
University of Calgary

ROR
https://ror.org/03yjb2x39

Funder(s)

Funder type
Industry

Funder Name
Alberta Precision Laboratories

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Byron M. Berenger (byron.berenger@ucalgary.ca) when the study is published in a peer-reviewed journal.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/11/2022	18/11/2022	Yes	No
Preprint results		06/06/2022	18/07/2022	No	No