ISRCTN85858267 https://doi.org/10.1186/ISRCTN85858267

Using artificial intelligence as an aid to predict the risk of hospital readmission in patients with COVID-19

Submission date
09/02/2022

Recruitment status
No longer recruiting

Registration date
14/03/2022

Overall study status
Completed

Last Edited
19/10/2022

Condition category
Infections and Infestations

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Up to one-third of patients hospitalised with COVID-19 are readmitted to hospital within 4 months. This figure is higher than would be expected. These patients are more likely to have poorer long-term health, and some will die. It is not known why some patients are more likely to be readmitted, but it might be because they are older, living with other illnesses, living in lower-income areas, recovering from severe COVID-19, unvaccinated, receiving treatment or medication that suppress their immune system, or from an ethnic minority. The aim of this study is to use artificial intelligence as an aid to predict the risk of hospital readmission in patients with COVID-19.

Who can participate?
Patients aged 18 years and older with COVID-19 in England and Scotland

What does the study involve?
The researchers will use data from 220,000 hospital patients within the UK. They have linked these data to general practice and hospital NHS data in England and Scotland, vaccination data and data regarding virus variants. The dataset is necessary to provide detail on patients' hospital stay, and NHS data will determine the details of readmission. Artificial intelligence approaches will be used to determine the risk of readmission using information about a patient's disease, treatment and status at discharge. A risk calculator will be built, validated, and made available to the public and healthcare staff while undergoing regulatory approval.

What are the possible benefits and risks of participating?
Identifying those at risk of hospital readmission is important for three reasons. It will help identify patients most likely to have long-term health problems after COVID-19, It will allow safer discharge decisions, and it may enable targeted programmes to support patients at home and reduce the chance of readmission.

Where is the study run from?
University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
November 2021 to January 2023

Who is funding the study?
1. Health Data Research UK (HDRUK)
2. The Alan Turing Institute (UK)

Who is the main contact?
Prof. Ewen M Harrison
ewen.harrison@ed.ac.uk

Study website
https://www.hdruk.ac.uk/projects/using-artificial-intelligence-as-an-aid-to-predict-the-risk-of-hospital-readmission-in-patients-with-covid-19/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Ewen Harrison

ORCID ID
http://orcid.org/0000-0002-5018-3066

Contact details
Centre for Medical Informatics, Usher Institute
Edinburgh
United Kingdom
EH16 4UX
+44 (0)1312423611
ewen.harrison@ed.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
126600

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
11519663, IRAS 126600

Study information

Scientific Title
Predicting unplanned hospital readmission prior to discharge in patients with COVID-19: development, validation, and implementation of a machine-learning-based risk prediction model

Acronym
4C-R

Study objectives
Research questions:
1. What factors are associated with hospital readmission of COVID-19 patients?
2. What are the consequences of re-admission?
3. Can we reliably predict unplanned hospital readmission with machine learning?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2020, South Central - Oxford C Research Ethics Committee (address: not available; +44 (0)207 104 8226, +44 (0)207 104 8241, +44 (0)207 104 8256; oxfordc.rec@hra.nhs.uk), REC ref: 13/SC/0149
Approved 01/05/2020, Scotland A Research Ethics Committee (address: not available; +44 (0) 131465 5680; Manx.Neill@nhslothian.scot.nhs.uk), REC ref: 20/SS/0028

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Clinical prediction model development

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Trajectory modelling: understanding readmission and its consequences:
First, the researchers will examine the factors associated with readmission with time-to-event

models, accounting for death as a competing event. Multilevel binary logistic regression will be used to examine the consequences associated with readmission, including the complications of disease and mortality.

Risk prediction model development:
TRIPOD best practice guidelines will be used. Temporal and geographical validation sets will be held out. Derivation data will be used to define baseline models using logistic regression. A systematic examination of additional algorithms will be undertaken, including discriminative and generative approaches, as well as different neural network architectures. The researchers will pay particular attention to model explainabillity by design. K-fold cross-validation will be used, and performance assessed with area under receiver operator curves, sensitivity (recall), specificity, precision, and accuracy. Calibration will be performed, and validation using the holdout datasets.

Intervention Type
Other

Primary outcome measure
Hospital readmission measured using NHS data at 30 and 90 days

Secondary outcome measures
Mortality measured using NHS data at 30 and 90 days

Overall study start date
01/11/2021

Completion date
31/01/2023

Eligibility

Key inclusion criteria
Consecutive patients (ISARIC4C/CO-CIN) aged 18 years and older with a completed index admission for COVID-19 in England and Scotland

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
5261

Key exclusion criteria
Age <18 years

Date of first enrolment
14/02/2022

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
University of Edinburgh
Old College
South Bridge
Edinburgh
United Kingdom
EH8 9YL

Study participating centre
University of Liverpool
Liverpool
United Kingdom
L1 8JX

Sponsor information

Organisation
University of Edinburgh

Sponsor details
NINE Bioquarter
Edinburgh
Scotland
United Kingdom
EH16 4UX

+44 (0)131 650 1000
enquiries@ed.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Charity

Funder Name
Health Data Research UK

Funder Name
Alan Turing Institute

Alternative Name(s)
The Alan Turing Institute, ATI

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers are committed to meaningfully collaborating with public members throughout this project and a lay member (Weatherill) and PPI Research Fellow (Jackson) jointly lead a dedicated PPIE Work Package. The researchers will continue to involve the EAVE II PAG in PPIE

activities throughout the project lifecycle. In addition, they have existing relationships with the Long COVID Scotland Action Group and minority ethnic and faith groups who they will engage with to ensure their perspectives are included in this work.

The EAVE II PAG and Weatherill have actively contributed to developing the research questions, designing the research, and producing this application. Weatherill is a member of the project management group and will attend project meetings ensuring the public perspective is included throughout the project.

PPIE members will be involved in decision-making and have influence over the direction of the research. Their involvement in interpreting findings will bring invaluable public perspective to discussions and helping keep the research grounded in the real world. The public members are viewed as colleagues and will be included in opportunities to co-author papers and attend conferences. The researchers will report on their PPIE activities, measure impact and disseminate in journals and conferences to promote the best practice of PPIE in healthcare research.

To help increase public confidence in healthcare data usage, the researchers will work with their PPIE groups to create engaging messages to showcase their project to a lay audience. They will evaluate their PPIE activities to continue to improve how we work with patients, the public, and communities.

Intention to publish date
31/01/2023

Individual participant data (IPD) sharing plan
Applications for use of this data by researchers can be made via the HDRUK Gateway.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No