ISRCTN86554504 https://doi.org/10.1186/ISRCTN86554504

40 Steps to Safety: Can comparing blood oxygen levels before and after a person has walked 40 steps help to decide whether they can be safely discharged from hospital?

Submission date
27/09/2020

Recruitment status
No longer recruiting

Registration date
31/08/2023

Overall study status
Completed

Last Edited
06/09/2023

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Patients with suspected infection with COVID-19 might appear well but their oxygen levels might dangerously drop on exertion. The National Health Service In England has suggested to ask patients to walk for 40 steps on the flat to assure oxygen levels stay stable before allowing patients with suspected COVID to return home. The 40-steps test has not been used for this purpose before. The aim of this study is to investigate the ability of this test to detect low blood oxygen levels in patients who appear well, to find out whether developing low oxygen levels with exercise can be used to identify patients who are at higher risk of becoming unwell in the future.

Who can participate?
Acutely unwell patients who attend hospitals or are assessed by paramedic crews

What does the study involve?
Participants are asked to undertake the 40 steps test. This will involve taking 40 steps on the spot at their normal walking speed. Researchers will check whether oxygen levels or heart rate change after the test. After 30 days researchers will follow up the participants.

What are the possible benefits and risks of participating?
Participants will be contributing to important research which could help develop a better way to identify patients who can be safely discharged from hospital. They will also be helping us to better understand the normal response to exercise, and how this is different in a range of medical conditions, including in COVID-19.
The researchers anticipate that taking part in this study is generally very safe. However, there is a small possibility of a fall, which could result in injury, whilst doing the 40-step test.
Some participants may experience symptoms such as breathlessness, light-headedness, or chest pain whilst taking part in the study.

Where is the study run from?
Betsi Cadwaladr University Health Board (UK)

When is the study starting and how long is it expected to run for?
September 2020 to May 2022

Who is funding the study?
Betsi Cadwaladr University Health Board (UK)

Who is the main contact?
Dr Christian P Subbe, christian.subbe@wales.nhs.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283998

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 283998

Study information

Scientific Title

Exertional desaturation as a marker of risk – Validation study for the 40-steps-test: A multi-centre prospective observational cohort study

Study objectives
Absence of desaturation on performing the 40-steps-test is a predictor of safe discharge from hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/10/2020, Wales Research Ethics Committee 5 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)7970 422139; Wales.REC5@wales.nhs.uk), ref: 20/WA/0286

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
All alert and mobile acutely ill patients considered for discharge to independent care including patients with suspected COVID-19

Interventions
Performance of the 40-steps-test and measurement of oxygen saturations and pulse rate prior to the test and after completion.

Intervention Type
Other

Primary outcome measure
Validation of the 40 steps on the spot test as a marker for safe discharge from hospital, assessed by collecting the following information from the participants' medical records:
1. Change in decision to discharge following the 40 steps test
2. Outcome at 30 days following the test (30-day hospital admission and 30-day mortality)

Secondary outcome measures

Normal values for the 40 steps test challenge in a range of age groups:
1. Oxygen saturation measured by oximeter
2. Heart rate measured by oximeter
3. Breathlessness measured by number of breaths per minute and by using the rating scale for dyspnoea
The above will be measured immediately after the 40 steps test and at 2 minutes after ending the test. Baseline values will be collected from medical records

Overall study start date
18/09/2020

Completion date
01/05/2022

Eligibility

Key inclusion criteria
1. Patients who are being considered for discharge to independent care
2. Willing and able to give informed consent for participation in the study
3. Independent, stable gait
4. Alert, attentive, coherent and calm

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Minor injuries
2. Elective surgery patients
3. Post-operative patients at discharge
4. Requires supplemental oxygen
5. Shortness of breath at rest (i.e. Borg or Numerical Rating Scale >=2)
6. Unstable angina
7. On long-term-oxygen therapy
8. Pregnancy as stated by patient
9. Oxygen saturation <95% on room air
10. Resting heart rate >100 bpm
11. Resting respiratory rate >25 bpm
12. ECG with signs of acute ischemia in patients where an ECG has been requested by the treating clinician
13. National Early Warning Score of 5 or more
14. Nursing home residents, or those being transferred to a nursing home or similar care facility

Date of first enrolment
30/11/2020

Date of final enrolment
26/10/2021

Locations

Countries of recruitment
Denmark

Netherlands

United Kingdom

Wales

Study participating centre
Ysbyty Gwynedd
Penrhosgarnedd
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United Kingdom
LL57 2PW

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

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Sponsor type
Hospital/treatment centre

Website
https://bcuhb.nhs.wales/hospitals/ysbyty-gwynedd/

ROR

https://ror.org/03awsb125

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Betsi Cadwaladr University Health Board

Alternative Name(s)
Betsi Cadwaladr University Local Health Board, Bwrdd Iechyd Prifysgol Betsi Cadwaladr, Health Board, Betsi Cadwaladr UHB, Betsi Cadwaladr Local Health Board, BCUHB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be published in peer-reviewed journals on completion of the trial.

Intention to publish date
01/01/2022

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?
Participant information sheet	version 1.2	30/12/2020	27/07/2023	No	Yes
Results article		20/04/2022	06/09/2023	Yes	No