# 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	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
27/09/2020		Protocol		
Registration date 31/08/2023	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 06/09/2023	Condition category Signs and Symptoms	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

#### Contact name

Dr Christian P Subbe

#### **ORCID ID**

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

283998

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

**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

#### Study type(s)

Screening

#### 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(s)

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)

### Key secondary outcome(s))

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

#### Completion date

# **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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

ΔII

#### 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

United Kingdom

Wales

Denmark

Netherlands

# Study participating centre Ysbyty Gwynedd

Penrhosgarnedd Bangor United Kingdom LL57 2PW

# Sponsor information

#### Organisation

Betsi Cadwaladr University Health Board

#### **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, Health Board, Betsi Cadwaladr UHB, Betsi Cadwaladr Local Health Board, Bwrdd Iechyd Prifysgol Betsi Cadwaladr, BCUHB

#### **Funding Body Type**

Government organisation

## **Funding Body Subtype**

Local government

#### Location

United Kingdom

# **Results and Publications**

## 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?
Results article		20/04/2022	06/09/2023	Yes	No
Participant information sheet	version 1.2	30/12/2020	27/07/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes