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The reliability of frailty assessment in intensive care

Submission date
12/07/2017

Recruitment status
No longer recruiting

Registration date
27/09/2017

Overall study status
Completed

Last Edited
14/06/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims
As national populations age, the proportion of older patients among those admitted to critical care has risen in many regions. Age unfortunately has negative prognostic implications for the outcome of critical illness and if faced with poor likelihood of a good outcome many older people may express a wish "not to be kept alive on life support". For an individual facing critical illness age by itself may be a fairly blunt indicator of likely outcome, and it seems that assessing "frailty" may in future help discussions between clinicians, patients and their relatives about the potential benefits of critical care treatments - and identify those who may need extra support with their longer-term recovery. The reliability of assessing frailty at the bedside in critical care (i.e. how closely do two separate assessments made by two different clinicians match each other?) needs research. The aim of this study is to determine the reliability of bedside frailty assessments.

Who can participate?
Adults aged 60 and older who are admitted to a critical care unit for 24 hours or more.

What does the study involve?
Participants take part in two interviews on the same day by two different members of the research team. The interview consists of unscripted questions to assess frailty, based on fitness, chronic disease, activity of daily living, dependence, mobility, and life expectancy. If participants are unable to participant due to severe illness, a proxy (a carer who is in contact with them on a regular basis and has known them for over five years) may be interviewed. The results from each frailty assessment are compared. The follow up consists of data that is collected for 30 days.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
This study is being run by the Betsi Cadwaladr University Health Board (UK) and takes place in eight health centres in the UK.

When is the study starting and how long is it expected to run for?
November 2016 to May 2018

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

Who is the main contact?
Dr Richard Pugh

Contact information

Type(s)
Public

Contact name
Dr Richard Pugh

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Additional identifiers

EudraCT/CTIS number

IRAS number
228370

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 228370

Study information

Scientific Title
Frailty Assessment Reliability in the Intensive Care Unit

Acronym
FAR-ICU

Study objectives
The inter-rater reliability of bedside frailty assessment is unclear.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 4, 07/06/2017, 17/WA/0168

Study design
Multi-centre observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Frailty

Interventions
Potential participants (whether patient or proxy) are screened for eligibility, approached for participation and ask to provide consent to participate during at time of ICU admission.

Following consent participants take part in two interviews each conducted by a different member of the clinical team. Each interview takes less than 15 minutes. The interviews are conducted during the ICU admission, typically both on the same day, but by different clinicians. The interview consists of unscripted questions that enable the clinician to assess frailty according to the Dalhousie Clinical Frailty Scale – which relies on an interpretation of fitness, chronic disease, activities of daily living, dependence, mobility, resilience to acute illness and life expectancy.

Some critically ill patients who are not be able to participate in these discussions because of the severity of their illness are allowed, under these circumstances, a proxy (somebody who has known them for a long time [>5 years] and is in contact with them on a regular basis, for example, a close member of family) may agree to be interviewed.

The comparisons are made between the CFS assessments made by two groups of clinicians (a “senior” and a “junior” group, depending on the relative number of years of post-registration experience of each of the two clinicians making the assessment).

Follow-up is done in the form of routinely collected data, censored at 30 days and there is no direct participant involvement in follow-up.

Intervention Type
Behavioural

Primary outcome measure
1. Inter-rater reliability of frailty assessment (comparing the assessment of two groups of clinicians using the Clinical Frailty Scale) is measured using the kappa statistic after the interviews.
2. Frailty is measured using the clinical frailty scale at time of interview.

Secondary outcome measures
1. Hospital mortality is measured using collected data at 30 days
2. Critical care length of stay is measured using routinely collected data at 30 days.

Overall study start date
01/11/2016

Completion date
01/05/2018

Eligibility

Key inclusion criteria
1. Admitted to Critical Care units
2. Aged 60 years and over
3. Anticipated stay greater than 24 hours

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100

Total final enrolment
101

Key exclusion criteria
1. Aged less than 60 years
2. Anticipated Critical Care stay or survival less than 24 hours
3. Where patient's condition prevents them from being interviewed and there are no other individuals qualified to act as proxy
4. No capacity to consent to participation nor anyone able to act as personal consultee

Date of first enrolment
01/10/2017

Date of final enrolment
01/11/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Wales

Study participating centre
Glan Clwyd Hospital
Rhuddlan Road
Bodelwyddan
United Kingdom
LL18 5UJ

Study participating centre
Ysbyty Gwynedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Drive
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

Study participating centre

Morriston Hospital
Heol Maes Eglwys
Morriston
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
Royal Glamorgan Hospital
Ynysmaerdy
Llantrisant
United Kingdom
CF72 8XR

Study participating centre
Prince Charles Hospital
Gurnos Road
Merthyr Tydfil
United Kingdom
CF47 9DT

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

Sponsor details
Ysbyty Gwynedd
Bangor
Wales
United Kingdom
LL57 2PW

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Betsi Cadwaladr University Health Board

Results and Publications

Publication and dissemination plan
Study protocol will be available on request. Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Richard Pugh (richard.pugh@wales.nhs.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	05/04/2017	27/09/2017	No	Yes
Results article	results	01/06/2019	14/06/2019	Yes	No
HRA research summary			28/06/2023	No	No