Assessing the feasibility and reliability of an ultrasound-based method of measuring the geniohyoid muscle in mechanically ventilated patients – a protocol for an observational study

Version 2.1 – 28/04/2026

Part A – General Study Information

1.1 Administrative Details

Item	Description
Title	Assessing the feasibility and reliability of an ultrasound-based method of measuring the geniohyoid muscle in mechanically ventilated patients – a protocol for an observational study
Short title	The geniohyoid muscle in critical illness
Protocol number	Version 2.0 – 15th January 2026
Protocol Summary	See part A, section 4
Sponsor	North Cheshire and Mersey NHS Foundation Trust
Sponsor approval number	1
Funding	None
Conflict of interest	None
Chief Investigator	Dr Peter Turton, Consultant in Intensive Care Medicine
Co-Investigator	An appointed JCF/F2 doctor TBC
Investigator affiliation	North Cheshire and Mersey NHS Foundation Trust
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1.2 Approvals

Type	Number
Sponsor's approval	W0001
IRAS number	341070
REC	North West – Greater Manchester South
REC approval number	26/NW/0011
HRA approval number	
Study registration identifier	Registration with clinicaltrials.gov TBC

2 - Study Summary

Population	Mechanically ventilated patients, in an Intensive Care Unit (ICU)
Intervention/Comparator	Not applicable
Measures	1) Cross-sectional area (CSA) of the Geniohyoid (GH) muscle in the coronal plane 2) CSA of GH in the sagittal plane 3) Echogenicity of GH in coronal plane 4) Echogenicity of GH in sagittal plane
Number of measures	Three – two by first investigator, one by second investigator
Primary outcome	Proportion of patients in which suitable measure 1 is obtained.
Secondary outcomes	1) Proportion of patients in which suitable measures 2, 3, 4 are obtained 2) Intra-rater agreement of measures 1-4 3) Inter-rater agreement of measures 1-4 4) Construction of Bland-Altman plots for outcomes 2 and 3. 5) Summary means and standard errors of measures 1-4
Total number of visits by research team	One
Estimated participant time in study	30 minutes
Follow up visits	None

3 - Plain Language Summary

3.1 Introduction

We know that many patients lose muscle due to being unwell in an intensive care unit. This muscle loss can lead to weakness of the arms and legs when they leave the unit, and when they go home. For many years we have measured the size of these arm and leg muscles using an ultrasound machine, to take a picture of the muscles.

We also know that patients who are on a ventilator (or "breathing machine") often have problems swallowing when the breathing tube is removed from their mouth. We think that this is because the muscles of swallowing may also shrink. One of these muscles sits under the jaw and can be measured with ultrasound – the method has been shown to be accurate and reliable in awake volunteers, but these volunteers are usually sat upright in a chair with their mouth closed.

Before we can measure whether these muscles get smaller, we need to assess whether the method we have chosen is suitable in patients on a ventilator; these patients are lying in bed, and their mouths are open slightly due to the breathing tube.

3.2 Proposed Method

We would like to measure the size of a muscle under the jaw (called the geniohyoid muscle) in patients who are sedated and have a breathing tube in their mouth connected to a ventilator.

Using a normal hospital ultrasound machine, one researcher will place the ultrasound probe under the patient's jaw. When they are happy the probe is in the right place, they will take a picture of the muscle and measure its size and thickness. After a short break, the researcher will repeat this process. After a second short break, another researcher who did not watch the first researcher will also place the probe under the jaw and take a picture of the muscle.

We can then use these measurements to answer the following questions:

1) How many patients scanned produced images that could be measured?
2) How consistent are the measurements if one person measures the same muscle twice?
3) If two people measure the same muscle, do their measurements agree with each other?

The patients will be under sedation when they take part in the study. Because of this, they cannot consent to take part in the study. We would ask the patient's next of kin or carer to advise on whether the patient would want to take part. When the patient is awake and has the breathing tube removed, we would ask them to sign a consent form to use their data.

3.3 Frequently Asked Questions

How long will it take?

At most 30 minutes.

Will they be measured over several days?

No, we will do one set of measurements. The patient's involvement in the study ends after the second researcher has completed their measurements. There will be no follow-up or further ultrasound scans.

Does it hurt?

In order to get the best images, we have to press the probe very lightly under the jaw. The patients will be under sedation. We do not anticipate the ultrasound causing pain to the patient. Their head will be on one pillow, and the head will not be moved into any extreme positions.

Why are you doing this?

It is hoped that this method a measuring the muscles under the jaw will prove to be reliable and consistent. We can then design a second study where we measure how the size of this muscle changes over time, using repeated scans over several days.

This would give us new information about how swallowing muscles are affected by critical illness.

4 Protocol Abstract

4.1 Introduction

Many patients who are mechanically ventilated due to critical illness have difficulty in swallowing after the endotracheal tube is removed, a phenomenon known as Post Extubation Dsyphagia (PED). Although multifactorial, atrophy of the swallowing muscles is a potential cause.

Ultrasound is a commonly used investigative modality for the measurement of muscles in critically unwell patients. Measurements can be performed repeatedly over time to track changes in muscle size during the course of a patient's admission. In critically unwell patients, much of the research is focussed on muscles of the limbs and trunk. The muscles of swallowing have been measured using ultrasound, but in awake patients adopting an optimal seated position. Critically unwell patients are bedbound, and the endotracheal tube leaves their mouth in an open position. Before embarking on a study using ultrasound to attempt to track changes in muscle size in the muscles of swallowing, we first wish to assess if such a method is both feasible and reliable.

4.2 Methods

Critically unwell patients who are sedated and mechanically ventilated will be recruited into the study after discussion with a patient's personal consultee. The geniohyoid (GH) muscle will be scanned in both the coronal and sagittal planes. The patient will be scanned three times. Twice by one assessor, and once by a second assessor. Cross sectional areas (CSA) of GH will be measured at a later time using image processing software (ImageJ, NIH, USA). Echogenicity, a measurement of the brightness of muscle on ultrasound, will also be assessed.

4.3 Results

The primary outcome is to obtain the proportion of patients whose images from ultrasound can provide satisfactory measurement data, in each plane. Furthermore, we will assess the repeatability of each measurement by calculating the intra-rater agreement, and the inter-rater agreement to assess agreement between assessors. An estimate of the mean CSA in each plane will be calculated.

4.4 Conclusions

This preliminary data will give us an estimate of the proportion of patients who can provide satisfactory images of GH, in preparation for a larger study assessing longitudinal changes in CSA. Further, the study will give data on both the inter- and intra-rather agreement of the method.

Part B – Introduction

5 Literature Review

5.1 Background to the study

Dysphagia is a common consequence of prolonged mechanical ventilation during critical illness(1). A recent meta-analysis estimated the incidence of Post-Extubation Dysphagia (PED) at 41%, and of those with PED, 36% suffer from silent aspiration (2), with older patients at higher risk of delayed resolution of their swallowing impairment after aspiration (3).

PED is defined as “the inability to effectively transfer food from the mouth into the stomach” after a period of mechanical ventilation (4). The causes of PED are often multifactorial, including direct trauma from the endotracheal tube, loss of oropharyngeal sensation, and impaired neuromuscular function (5). Muscle atrophy during critical illness is well described, affecting muscles of the limbs (6), trunk (7,8), and respiratory system (9,10). Such atrophy will result in reductions in muscular strength that may impact swallowing and secretion clearance post extubation. In Computed Tomography studies, age related atrophy of swallowing muscles has been demonstrated, and smaller cross sectional areas of swallowing muscles are found in people at risk of aspiration (11)

There are several muscles whose cross-sectional area, thickness and echogenicity can be assessed by ultrasound, including the geniohyoid (GH) (12), and digastric muscles (13). Using these methods, GH atrophy has been identified in patients with swallowing disorders relating Duchenne’s Muscular Dystrophy (14), and in patients

with sarcopenic dysphagia, a positive correlation exists between GH area and maximum tongue pressures (15). However, in critically ill patients, less is known about whether rapid atrophy of the muscles of swallowing has an effect on swallowing after liberation from mechanical ventilation. In addition, we are unsure if the methods used to assess muscle area and echogenicity are suitable for mechanically ventilated patients; whilst dynamic methods can be carried out to measure muscle displacement in awake patients (16), the nature of mechanically ventilated and sedated patients limits us to static assessments of muscle size and echogenicity (brightness).

5.2 Prior research

Methods of GH measurement and reliability

The GH muscle can easily be accessed by ultrasound methods. It lies between the mandible and hyoid bones, and can be measured in both transverse and sagittal planes, demonstrating little variance between measures and also a training effect (17). In healthy volunteers, intra-class correlations for repeated measures of GH thickness are greater than 0.9 (18), and inter-tester reliability of both area and length at rest are significant (0.88 and 0.66 respectively, $p<0.001$) (19).

Effects of positioning

Another limiting factor to consider in mechanically ventilated patients is the effects of position. Many studies assessing both static and dynamic measures are performed in healthy volunteers and in a seated position (20). Mechanically ventilated patients are positioned in a semi-recumbent position, and in addition have their mouths

partially open due to the endotracheal tube, which in itself may present an obstruction to ultrasonography.

5.3 Rationale

Quantification of CSA and echogenicity of GH has been well documented in a number of populations, producing results with high inter-rater and intra-rater agreement.

Skeletal muscle atrophy is common in critically unwell patients, and it's quantification with ultrasound is well described in the limbs, trunk and thorax. However, less is known about ultrasound's ability to measure CSA of the GH in mechanically ventilated patients.

We would be unable to achieve the optimal scanning conditions described in studies involving awake patients and healthy volunteers, and while these studies are performed with the participants' mouths closed, the mechanically ventilated patient has an open mouth to accommodate the endotracheal tube. In addition, sedation and the presence of an endotracheal prevents us from performing dynamic assessments of muscle contraction or hyoid bone displacement.

Because of this, we feel it wise to assess the feasibility of measuring CSA and echogenicity, using ultrasound from two different planes. This will help to inform any sample size calculations in a later study to assess muscle atrophy over the course of an intensive care admission. It will also aid in deciding which ultrasound plane to use in such a later study.

6 Aims and Objectives

6.1 Aims

The aim of the study is to assess the feasibility of using ultrasound to accurately measure the CSA of the GH muscle, in patients who are sedated and mechanically ventilated via an endotracheal tube.

6.2 Objectives

6.2.1 Primary Objective

To obtain an estimate for the proportion of patients in which satisfactory images can be measured, in both measured planes (coronal and sagittal views). An "unsatisfactory" image is due to either the investigator being unable to adequately visualise the GH muscle with the probe (e.g. due to subcutaneous fat, difficult patient positioning, or when an image has been obtained, the offline CSA measurement cannot be performed due to inadequate visualisation of the muscle's fascial border. In addition, the co-efficient of variance of the three images taken must be less than 5%.

The primary objective will be achieved by calculating the proportion of patients in whom satisfactory images were obtained and measured, and the 95% confidence interval. Separate proportions and confidence intervals will be constructed for the different ultrasound planes, one coronal and one sagittal.

6.2.2 Secondary objectives

The secondary objectives are to assess the inter-rater and intra-rater agreement of both CSA and echogenicity, in both ultrasound planes.

Part C – Methods

7 Study Design

7.1 Description

This is a single centre, observational study in which a cohort of one group of patients undergo one set of ultrasound measurements, to determine feasibility and agreement of measures.

7.2 Study setting

The study will take place in the Intensive Care Unit on the Warrington Hospital site, part of the North Cheshire and Mersey NHS Foundation Trust.

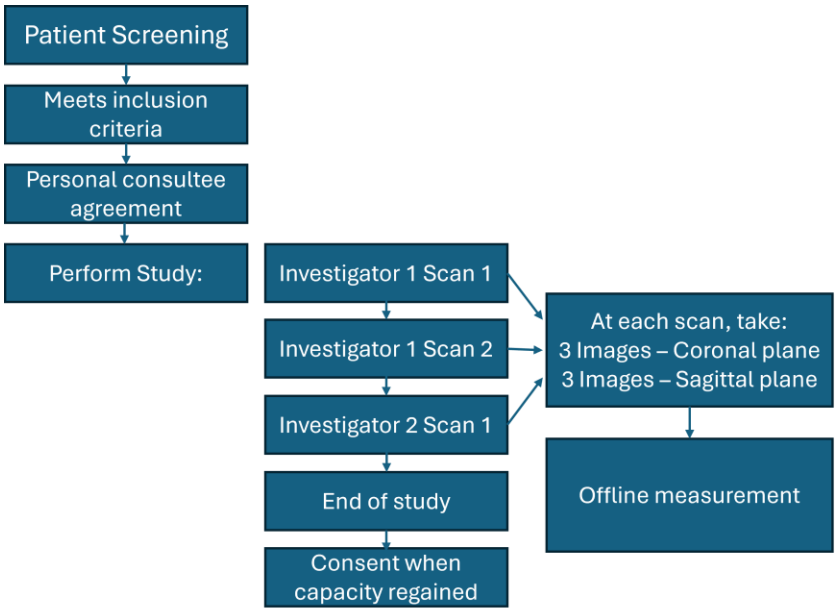
7.3 Study schedule

7.3.1 Participant schedule

Patients can be recruited to the study at any point in their admission, so long as they still have an endotracheal tube in-situ connected to a mechanical ventilator. When identified as eligible for the study, and a Consultee Declaration signed by next of kin, (see section x), both researchers will perform their ultrasound scans in the pattern laid out in the figure below. There should be a 5 to 10 minute gap between scans. It is expected that once the final scan has been completed, the patient's involvement in the study has ended, except to sign a consent form or decline to take part once the patient has regained capacity.

Note that the ultrasound scans do not need to be performed on the same day that a Consultee Declaration is signed, though this is preferable.

Figure 1 – Expected schedule of study



7.3.2 Study Schedule

An estimated schedule of the entire study is provided in table 1.

Table 1 – proposed study schedule

Stage	Estimated Time
Training and practise of researcher's scans	1 month
Image acquisition from participants	6 months
Offline image measurement	3 months
Data analysis	Less than 1 month
Dissemination – write up for publication	3 months

7.4 – Sample Size

The primary outcome of the study is the number of patients who produce satisfactory images that can measured offline (i.e. at a later date after scanning), expressed as a percentage of the total number of patients scanned. We define unsatisfactory images as the mean of three images which give a co-efficient of variation of more than 5%, or where identification of fascial borders is so difficult that a cross-sectional area cannot be ascertained.

Based on an assumption that 90% of patients will produce satisfactory images, a sample size of 30 with give a 95% confidence interval size of approximately 10%

Confidence interval = $1.96 \times \sqrt{(p \times (1-p) / n)}$

$CI = 1.96 \times \sqrt{(90 \times (10) /30)}$

CI = 10.74% with a range 79.26 to ~100%

Where p is the percentage of patients that will produce satisfactory images

7.5 Recruitment Selection

7.5.1 Inclusion Criteria

- Mechanically ventilated patient on the intensive care unit
- Endotracheal tube via the mouth in-situ (size 7.0 and above)
- Can be recruited at any time during their admission

7.5.2 Exclusion Criteria

- Ventilated via a nasal endotracheal tube
- Ventilated via a tracheostomy
- Ventilated via a micro-endotracheal tube
- Any previous or active history of head and neck cancer
- Any previous head and neck surgery (excluding tonsillectomy and adenoidectomy)
- Any cranio-facial deformity that would render access to the jaw difficult, including but not limited to short thymo-mental distance
- Any neuromuscular disorder, including previous stroke
- Any previous history of dysphagia or swallowing disorder
- Pregnant patients
- Patients under 18 years of age
- Agitation or movement that would make measurement difficult or inaccurate

7.6 Data Collection

7.6.1 Baseline variables

These are summarised in table 2.

Table 2 – Summary of individual data collected per patient

Variable	Unit of measurement	Data source	Summary measure
Age	Years	Notes	Mean, standard deviation
Sex	N/A	Notes	Count (n, %)
Weight	Kilograms (Kg)	Notes	Mean, standard deviation
Height	Metres (m)	Notes, or measured	Mean, standard deviation
Body Mass Index	Kg/m^2	Derived from height and weight	Mean, standard deviation
Length of ventilation	Days	Nursing charts	Median, IQR
Size of endotracheal tube	Millimetres (mm)	Nursing charts	Mean, standard deviation

7.6.2 Collected variables

Each patient will be scanned three times, in the following pattern:

- Scanned by investigator A, first scan, coronal and sagittal views
- 5 – 10 minute break
- Scanned by investigator A, second scan, coronal and sagittal views
- 5 – 10 minute break
- Scanned by investigator B, only scan, coronal and sagittal views.

At each view, three images will be obtained. Therefore, at each scan, 6 images should be obtained (3 coronal, 3 sagital). Therefore, per patient, 18 images will be obtained and measured (12 from investigator one, and 6 from investigator 2).

Three images are taken so that when offline measurement is performed, the mean of these 3 images is what is then used for data analysis. The co-efficient of variation will also be calculated, aiming for a value of less from 5%. Offline measurement of CSA and echogenicity will be performed away from the patient, using a desktop computer and image analysis software (ImageJ, NIH, USA). The intended data collection (per patient) for offline measurement would then be collected on a spreadsheet as follows (table 3).

Table 3 – Proposed data collection tool for each individual patient

Patient 1	Investigator A Scan 1				Investigator A Scan 2				Investigator B Scan 1			
Image	1	2	3	Mean	1	2	3	Mean	1	2	3	Mean
Coronal CSA				*A*				*B*				*C*
Sagital CSA				*D*				*E*				*F*
Coronal Echo				*G*				*H*				*I*
Sagittal Echo				*J*				*K*				*L*

These mean values from the images would then be transferred to a table for all patients (Table 4).

Table 4 – Proposed data collection tool for the entire sample

	Coronal CSA			Sagittal CSA			Coronal Echo			Sagittal Echo		
	A1	A2	B1	A1	A2	B2	A1	A2	B2	A1	A2	B2
Pt 01	*A*	*B*	*C*	*D*	*E*	*F*	*G*	*H*	*I*	*J*	*K*	*L*
Pt 02												
Pt 03												
…												

Where A1- Investigator A Scan 1, A2 – Investigator A Scan 2, B1 – Investigator B Scan 2

After statistical analysis, these means from this data set would then form the following final results (tables 5 and 6).

Table 5 – Proposed final results table of mean differences for the entire sample

	Investigator A				Investigator B		
	Measure 1	Measure 2	Mean Diff*	P-value	Measure 3	Mean Diff**	P-value
Coronal CSA (cm^2, mean [SD]							
Sagittal CSA (cm^2, mean [SD]							
Coronal Echogenicity***							
Sagittal Echogenicity							

* Mean difference between measures 1 & 2 from Investigator A. ** mean difference between measures 1&3 between Investigators A and B. ***echogenicity has no units of measurement.

Table 6 – Proposed table of results (ICC) for the entire sample

	Coronal plane		Sagittal plane	
	CSA	Echogenicity	CSA	Echogenicity
Intra-rater agreement (ICC, p-value)				
Intra-rater agreement (ICC, p-value)				

7.7 Method of ultrasound image acquisition

7.7.1 Positioning

Bed: Patients will be lying in supine.

Head: The head will rest on one pillow, in a neutral position. The should be no extension or flexion of the cervical spine.

Body/legs: Lying flat to the bed, legs extended, however a pillow under the knees is allowable.

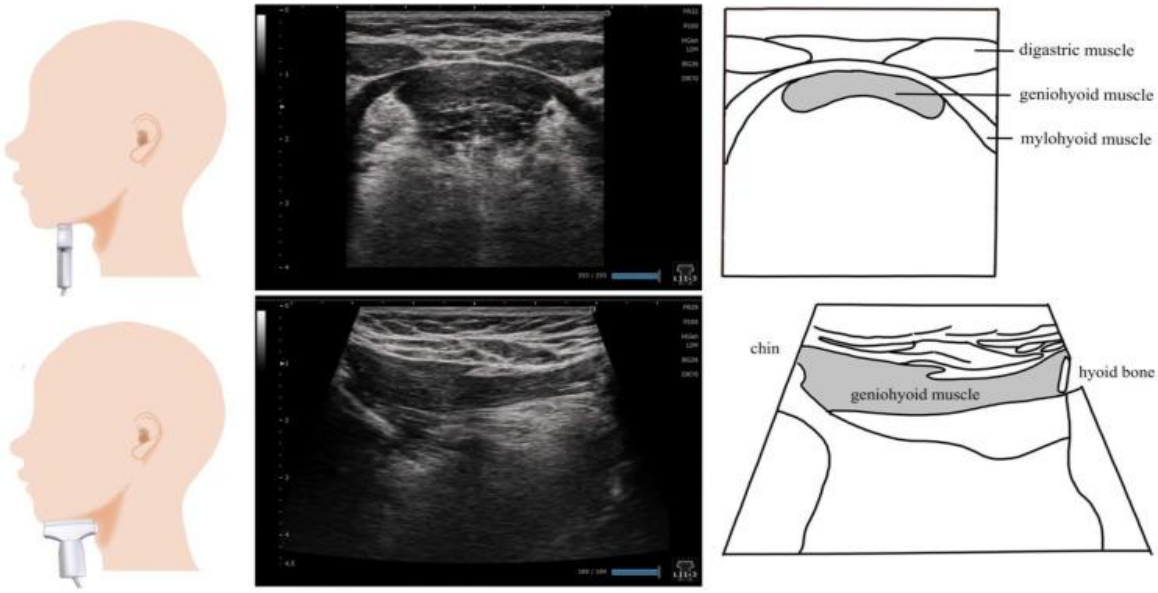
7.7.2 Ultrasound method

Two ultrasound methods will be used for image acquisition, and these are summarised in table 7. An example figure (figure 2) taken from the literature is provided below.

Table 7 – Summary ultrasound approaches

View	Coronal	Sagittal
Probe	High frequency Linear	Low frequency Curvi-linear
Landmark	Mid-point between hyoid bone and mental bone	Midline, running from the mental bone backwards

Figure 2 - Representative placement of probes and expected imaging for each technique



Legend: Top – coronal imaging using a linear probe. Bottom – sagittal imaging using a curvilinear probe. Reference x.

7.7.3 Offline imaging measurement

Images will be saved in JPEG format before being exported via encrypted USB stick, and then transferred to a secure, password protected computer. No images will have any identifying information either on the image or in the file name. Images will be identified in saved folders listed by their sequential enrolment number (e.g. 01, 02, 03 etc) into the study. As a result, no patient could be identified by looking at the images or knowing their enrolment number.

Muscle image measurement will be performed using ImageJ (NIH, United States of America). Cross-sectional area will be measured using the free-hand cross-section

tool, and echogenicity will be measured the histogram tool. These cross sectional areas will be measured in pixels, and therefore, in addition to measuring each muscle's area, each image will have an on-screen calliper (depth in cm), which will need to be measured to convert pixels to areas in square centimetres.

All images will be measured by one investigator, with a sample of images measured again by a second investigator.

7.7.4 Blinding

As this is a single sample study, the patients and investigators cannot be blinded in terms of allocation. However, blinding of data will be achieved in the following ways:

- When the first investigator performs their scans, they will avoid using the ultrasound machine's own measurement tools, so as not to bias their second measurement.
- The second investigator will not be present when the first investigator performs their scans.
- The first investigator will not be present when the second investigator performs their scans
- No measurements will be made using the ultrasound machine's measurement function.
- By the time of offline measurement, patients will be identified only as their enrolment number.
- When a sample of images are measured offline by another investigator, they will not have access to the first investigator's offline measurements.

7.7.5 Potential biases

Much of these are dealt with in the blinding procedures, however an additional measurement bias may occur based on compression of the muscle, for example one investigator pressing the probe to the skin too firmly and thus creating a smaller cross-sectional area. It is common to therefore use a thick layer of water-based ultrasound gel to prevent inadvertent compression.

7.8 Data analysis

7.8.1 Statistical plan

Paragraph 7.6.2 describes how the data will be processed from individual measurements from each image, to summary measures used for final analysis, but will be summarised here.

7.8.1.1 Primary outcome

The primary outcome is to count how many patients out of the entire sample could provide images that are measurable. Patients' images could be rejected from measurement either because an appropriate image could not be obtained (e.g. the probe couldn't be placed satisfactorily), or that the fascial borders used to delineate the muscle area could not be seen adequately during offline measurement.

The number of remaining patients who could provide satisfactory images that were measured offline will be divided by the total number of recruited patients, to give a proportion of patients who gave measurable images, plus a 95% confidence interval for that proportion. Note that separate proportions will be generated for the coronal and sagittal views of the muscles.

7.8.1.2 Secondary outcomes

In patients where images are measured appropriately, it is expected that for each muscle view (coronal and sagittal), the following summary measures for each patient would be generated.

- Mean CSA, Investigator A, measurement 1 (A)
- Mean CSA, Investigator A, measurement 2 (B)
- Mean CSA, Investigator B, single measurement (C)

For each muscle view, summary sample means and standard deviations will be generated. Mean differences between measures (A) and (B), and between measures (A) and (C) will be calculated, to assess sample differences in intra- and inter investigator measures. These mean differences will also be assessed with 95% confidence intervals. Bland-Altman plots will also be constructed.

In addition, intra-class correlation coefficients will calculated between measures (A) and (B) for repeatability and between (A) and (C) for absolute agreement between investigators. ICC values will be accompanied by p-values, and a p-value less than 0.05 would suggest statistically significant ICC value.

This process will be repeated for each separate CSA by view, and also for echogenicity.

7.8.2 Missing data

As the primary outcome is to establish how many patients could provide acceptable images/measurements, this missing data would form part of the primary outcome. Means, mean differences and ICC values for secondary outcomes will be calculated with the remaining data provided.

7.8.3 Withdrawals, replacements and loss to follow up

Where a patient withdraws from study, we would not use any of their data, and they would not become part of either the numerator (number of patients with measurable images) or the denominator (total number of patients scanned) for determining the primary outcome measure. We would plan to replace a withdrawn patient with a replacement until the target sample size achieved, by recruiting the next suitable patient.

As there are no follow up measures planned, there should be no loss to follow up.

7.8.4 Data confidentiality

Study nominated appointee forms and consent forms will be held in the study file, which will be held in a locked cabinet in an office that can be locked.

Images will be transferred from the ultrasound machine to a password protected computer, again in a locked office. The method of transfer will be encrypted USB stick. No images will contain patient identifiable information and the folders of images will be labelled by their study number.

Spreadsheets containing image measurements and statistical calculations will be performed on password protected computers. Individual data will be identified only by their study number in the spreadsheet. Although baseline variables such as age, height, weight and sex will be recorded, this will not be enough to identify the patient.

No patient identifiable data will be recorded in the final data summaries used for publication or presentation. Where images are used for illustrative purposes, they will not be indentifiable.

7.9 Investigator training

One investigator has experience in musculoskeletal ultrasound for measurement of muscle thickness and cross sectional area, in both healthy volunteers and mechanically ventilated patient. A second investigator will go through a period of practice in healthy volunteers.

7.10 Study End Point

The study will be considered complete once all data collection has finished and the statistical analysis of the dataset is completed.

Part D – Ethical considerations

8 Ethics

8.1 Approvals

Approvals will be sought from a Research Ethics Committee with experience in studies where patients lack capacity. Further approvals will be required from the Health Research Authority, and the protocol will updated to reflect successful application.

Local sponsorship will be provided by North Cheshire and Mersey NHS Foundation Trust after review this protocol.

8.2 Recruitment processes

Patients will be mechanically ventilated and sedated and therefore unable to consent to the trial. The patient's next of kin will be approached by the study team to act as a nominated consultee. If the patient regains capacity to consent for themselves, they will be informed about their participation in the study and retrospective consent will be sought.

Patients will be screened by the study team to identify potential patients who meet the inclusion criteria. Eligible patients will be discussed with the medical team that day to assess if the medical condition or comorbidities preclude recruitment into the trial (for example, the medical team have decided to withdraw care).

The next of kin will be approached by a member of the study team. The aims of the study and a discussion of what would happen to their relative during the study will

take place, and an information leaflet will be given to the next of kin. At this point, there is no obligation to sign a consultee declaration form. The next of kin will be given time to think about whether they want their relative to take part, and they can discuss the study with other members of the family.

They will sign a consultee declaration form, acting as a consultee on behalf of their relative. Should they later decide to withdraw this declaration, the patient will be withdrawn from the study, and all data removed from the study, and any ultrasound images deleted.

Once the patient regains capacity, they will be approached by the study team, explaining the involvement in the study, and the aims of the study. They will again be given time to think about whether they want their data to be used in the study, and will be given an information leaflet to read. There is no time limit on this, and once ready, the patient will have to provide retrospective consent by signing the appropriate retrospective consent form. Should they decide that they did not want their data used, their data will be removed from the study, and all ultrasound images deleted.

As this study is not time-critical, we have opted against using a professional consultee declaration.

All study team members will have a valid Good Clinical Practise certificate.

9 Risks and harms to patients

9.1 Risks and harm

Ultrasound is a safe, non-invasive method of imaging muscle. We do not foresee any harms from performing the ultrasounds. The gel used on the probe is water-based.

However, as we are positioning the ultrasound probe under the chin, there is a risk of dislodgement of indwelling devices, for example, disconnection of the endotracheal tube from the ventilator. All mechanical ventilators on our unit have disconnection alarms as standard, and so any disconnection would be immediately witnessed and corrected.

Other devices, so such as central venous lines and nasogastric tubes are at risk of dislodgement due to the moving of the patient, however all of these devices are securely placed. Endotracheal tubes are fastened to the mouth, nasogastric tubes are taped to the skin and central venous lines are sutured to skin. We do not anticipate the risk of dislodgement to be any higher than when standard patient movements are performed. In addition, the patient's bedside nurse will be present. Patient's will be fully monitored before during and after the study.

Risk of data loss/breach is mitigated by anonymising all data relating to the study measurements. We have outlined how study folders, images and spreadsheets will be kept in locked and (where appropriate) password protected environments. Should someone from outside the study try to gain access to the images or data, the patients will not be identified.

9.2 Adverse Event Reporting

Adverse Event: any untoward medical occurrence involving a participant in the study.

Serious Adverse Event: an adverse event that results in death, is life-threatening, prolongs hospital admission, results in persistent disability or incapacity, or a congenital birth defect. This includes the immediate action taken to prevent these from occurring.

Pre – Specified Complications that are exempt from adverse event reporting:

- Dislodged nasogastric feeding tube
- Dislodged venous or arterial access device (arterial catheter, central venous catheter, peripheral venous catheter).
- Dislodged medical device, except for endotracheal tube.

Any other Serious Adverse Event that occurs during the study period (defined as from the signing of the nominated consultee form, until the final ultrasound is performed) will be reported to the sponsor.

9.3 Public and patient involvement

Some public and patient involvement has been performed via the NIHR Involve website. Participants answered an advert and were provided with the Plain English summary given in this protocol. There were two respondents, who understood the need for the study, and felt the plain English explanation was clear to them.

Part E – Dissemination

10 Publications and presentations

10.1 Publishing

We aim to publish the data in an international journal where appropriate. Data presented will be limited to summary means from the sample plus appropriate statistical analysis. No individual level data will be published, except for an anonymised specimen ultrasound image.

10.2 Presentations

Prior to publication we would aim to present this as a poster presentation at a national or international conference in the field of critical care medicine.

10.3 Other communications

Where required, a report will be made available to sponsors and to research ethics committees at the termination of the study.

10.4 Authorship eligibility

Authorship eligibility will be made in accordance with ICMJE guidelines.

Part F – Other considerations

11 Artificial intelligence

We confirm that no artificial intelligence was used in the creation of this protocol. Artificial intelligence will not be used in any way during the data collection, image analysis or statistical analysis.

12 Funding

Investigators will be funded from paid time within their own salaries. Pre-existing ultrasound equipment will be used on the critical care unit.

13 Data sharing

Protocols and summary measures from publications will be shared as needed. Reasonable access to anonymised individual patient level data (e.g. individual measurements) will be granted should a publishing journal have this as a pre-requisite for publication. We will not share images, consent or nominated consultee forms.

14 Open science

We will register with an observational studies registry if this is required.

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