Template Protocol for non-CTIMPs

Investigating whether the abdominal waist circumference or abdominal girth can be employed as an accurate estimate of abdominal wall depth.

This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE TRIAL

Investigating whether the abdominal waist circumference or abdominal girth can be employed as an accurate estimate of abdominal wall depth.

This is a cross-sectional study of computerised tomography scan (CT) derived patient abdominal wall depths correlated to patient waist circumference for the production of a nomogram to guide the recommended depth of veres needle entry during the establishment of primary access at laparoscopic entry.

SHORT TRIAL TITLE / ACRONYM

Investigating whether the waist circumference can be used as an estimator of the depth of the abdomen as measured from the belly button.

PROTOCOL VERSION NUMBER AND DATE

V1.0 December 2022

MAIN SPONSOR

University Hospital Bristol and Weston NHS Foundation Trust

FUNDERS

University of Bristol

STUDY COORDINATION CENTRE

N/A

NRES reference: xxx

RESEARCH REFERENCE NUMBERS

IRAS Number: 321171

ISRCTN Number: 43007

SPONSORS Number N/A

FUNDERS Number UKRI Grant No. EP/S023704/1

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date:
……/……/……
……

Name (please print):

Dr. Lynne Armstrong

Position:

Consultant Radiologist

Chief Investigator:

Signature: Date:
…… ……/……/……

Name: (please print):

Hermes Gadelha

Study Team

Chief Investigator	Hermes Gadelha
Co-investigator	Richard Scott, Chimwemwe Miti
Trial Co-Ordinator /Study Manager	Chimwemwe Miti
Sponsor	The University Hospital of Bristol and Weston NHS Foundation Trust (UHBW)
Funder(s)	Centre for Doctoral Training PhD Studentship funded by UKRI
Clinical Trials Unit	N/A
Key Protocol Contributors	Chimwemwe Miti, Hermes Gadelha
Statistician	N/A
Committees	Research & Innovation Group (UHBW)

For general queries, supply of Study documentation, and collection of data, please contact:

Study Coordinator: Chimwemwe Miti

Address: University of Bristol

E-mail: zb2006@bristol.ac.uk

Clinical Queries

Clinical queries should be directed to zb20006@bristol.ac.uk who will direct the query to the appropriate person.

Sponsor

The University Hospital of Bristol and Weston NHS Foundation Trust is the research Sponsor for this Study. For further information regarding the sponsorship conditions, please contact:

Chair of R&D Research & Innovation Group (RIG)

Level D, St Michael's Hospital, University Hospitals Bristol and Weston NHS Foundation Trust

Bristol, BS2 8EG

Funder

The student PhD project is supported by the EPSRC Digital Health and Care Centre for Doctoral Training (CDT) at the University of Bristol (UKRI Grant No. EP/S023704/1)

STUDY SUMMARY

This protocol describes the 'Waist Circumference as an Estimator of Abdominal Wall Depth' study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the Study. Problems relating to this Study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

WC	weight circumference
AWD	abdominal wall depth

TRIAL SUMMARY

TRIAL TITLE

Investigating whether the abdominal waist circumference or abdominal girth can be employed as an accurate estimate of abdominal wall depth.

SHORT TITLE

Investigating whether the waist circumference can be used as an estimator of the depth of the abdomen as measured from the belly button.

DESIGN

Observational Study (Correlational Research)

AIMS

To assess the correlation between abdominal wall depth and waist circumference

To use this information in establishing a nomogram according to weight circumference for recommended Veres needle entry depth.

OUTCOME MEASURES

At the end of the study, it will be expected that the following will have been achieved

1. Production of correlation equation connecting waist circumference and abdominal wall depth

2. Description of weight relationship to abdominal adiposity.

3. Establishment of a safety nomogram guiding Veres needle insertion according to category of body waist circumference.

POPULATION ELIGIBILITY

Any mobile adult patient undergoing elective abdominal Computed Tomography Imaging (CT) or Magnetic Resonance Imaging (MRI) scans.

SAMPLE SIZE

385

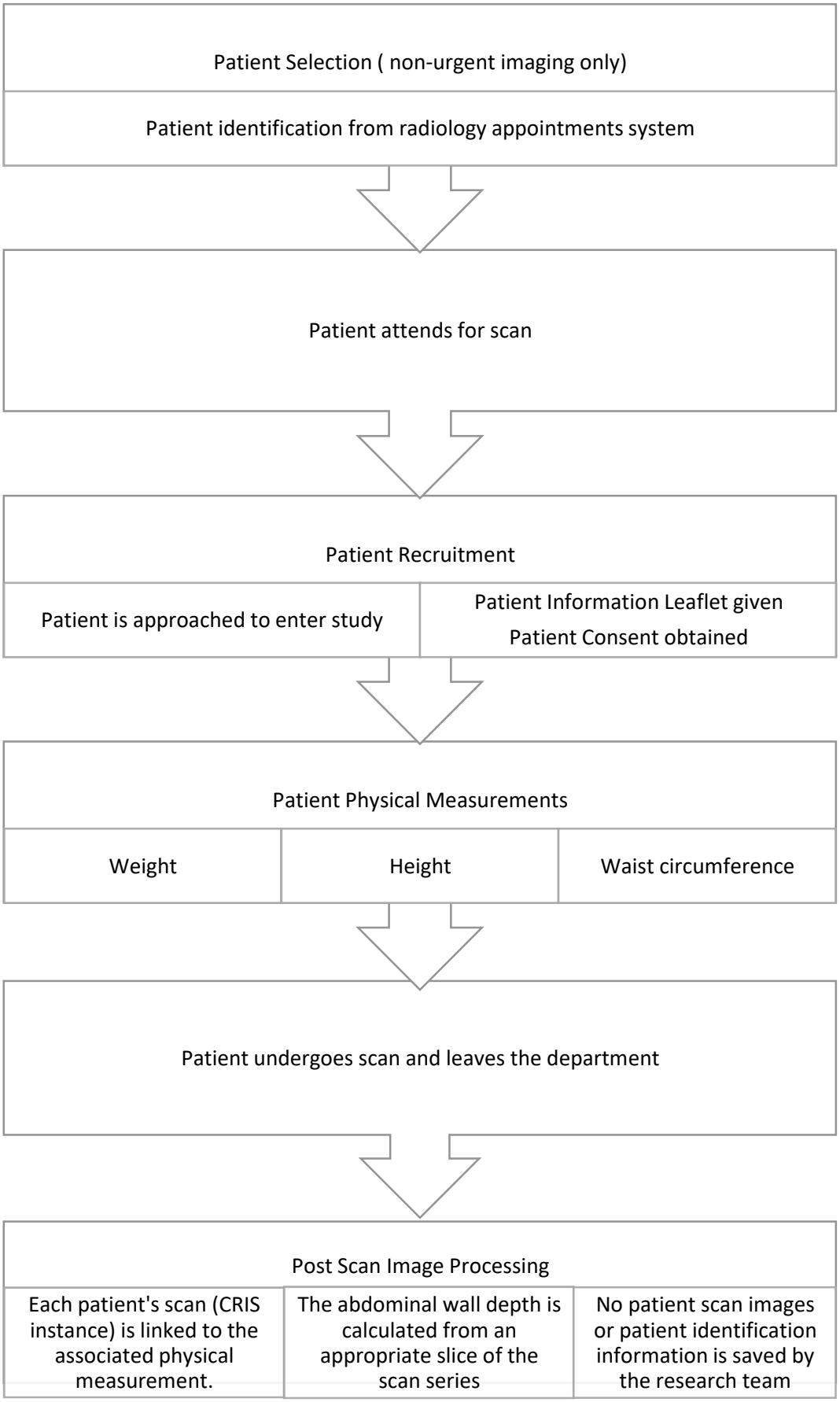
DURATION

1 month

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
EPSRC Digital Health and Care Centre for Doctoral Training (UKRI funded CDT)	**PhD Studentship at the University of Bristol**

TRIAL FLOW CHART



1. INTRODUCTION

1.1 BACKGROUND

Current abdominal entry during minimally invasive surgical techniques employs Veres needle insertion as one of the primary access mechanisms and by which a pneumoperitoneum within the peritoneal cavity is established. However, the procedure of needle insertion is of a blind nature with the result that entry associated injuries are unfortunately commonplace in laparoscopic abdominal surgery.

1.2 RATIONALE FOR CURRENT STUDY

This study seeks to assess whether the waist circumference can estimate the abdominal wall depth to a reliable degree of accuracy so as to be incorporated in a nomogram that would categorise suggested Veres needle abdominal insertion depth according to waist circumference range.

The research question is therefore 'Can the waist circumference be employed as an estimate of the abdominal wall depth?'

This would be helpful in guiding initial Veres entry into the abdominal cavity during laparoscopic (key-hole) or robotic surgery where entry is achieved blind without standardised depth advice. The traditional Body Mass Index (BMI) will also be taken to see if it makes a better correlation than abdominal girth. A study has previously been carried out analysing the relationship between BMI and vertical distance between umbilicus and retroperitoneal vessels (1) but we hypothesise waist circumference may be a better measure. The abdominal wall depth will be measured directly from abdominal Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scans with the waist, weight and height measurements to be physically taken from eligible consenting participants. The existence of a relationship that can be reliable in guiding needle depth investigation is hypothesised and requires further investigation.

Due to urgent need for safety mechanisms to be incorporated in the conduct of laparoscopic abdominal wall injury, this study attempts to provide some guidance into how deep the Veres needle should be inserted when a Veres needle is being used as the first entry abdominal device and insufflator. The study is aiming to improve safety in laparoscopic entry where a Veres needle is used by providing insertion depth guidance. It is aimed to reduce the number of failed entries or complicated entries.

2. STUDY OBJECTIVES

2.1 Primary Objectives

2.11. Investigate the correlation between waist circumference and abdominal wall depth through physical data collection. Waist circumferences will be obtained from patients as actual physical measurements and not estimated while the abdominal wall depth will be ascertained from each patient's corresponding cross sectional image.

2.12 Measure the abdominal wall depth of each participant from their cross sectional image. During laparoscopy, patients are in the same supine position and with patients required to be still during their scan, a reliable depth measurement can be taken as a proxy for their actual abdominal wall depth.

Produce descriptive statistics of the depths in the cohort of patients. Group each 1cm of abdominal wall depths by categories of waist circumference

2.13. Produce a nomogram for use as a predictor of abdominal wall depth.

2.2 Secondary Objectives

2.21. Assess the relationship of abdominal wall depth to BMI. Is BMI an inferior proxy measurement for abdominal wall depth?

2.22 How does the estimated (from CT scan) compare to actual wall depth (from actual Veres needle insertion depth in a future validation study-follow up of those patients who had surgery involving Veres needle pneumoperitoneum after their scan)

3. STUDY DESIGN

Quantitative Observational Study (Cross Sectional Study)

Participant physical measurements (waist circumference (cm), height(cm), weight(kg)) and the depth in centimetres of the associated abdominal wall depth taken from the corresponding radiological image.

These variables will be subjected to mathematical analysis in establishing correlations and building a nomogram.

A minimum of 385 participants and associated radiological scans of various weights(kg) will be recruited on a rolling basis. Recruitment will be at the time of patient presentation for their scan in the radiology department.

3.1 STUDY OUTCOME MEASURES

3.12 Production of correlation equation connecting waist circumference and abdominal wall depth

3.13 Description of weight relationship to abdominal adiposity.

3.14 Establishment of a safety nomogram guiding Veres needle insertion according to category of body waist circumference.

4. PARTICIPANT ENTRY

Participants undergoing routine abdominal or pelvic CT scans will have their waist circumference measured immediately prior to the scan commencing upon appropriate positioning. The weight and height are routinely collected physical measurements on arrival.

4.1 PRE-REGISTRATION EVALUATIONS

Participant body weight (kg), waist circumference (cm) and height (cm)

4.2 INCLUSION CRITERIA

Adults (patients aged above 18) undergoing cross sectional imaging that includes their abdomen.

Mobile patients, able to consent and volunteer their participation in the study.

4.3 EXCLUSION CRITERIA

Patients with uncorrected abdominal wall hernias or abdominal wall defects excluded as anatomical deviations from the norm can result in incorrect estimates of abdominal wall depth.

4.4 WITHDRAWAL CRITERIA

Free to withdraw at any time, without giving a reason at the point of measuring the physical body measurements.

5. ADVERSE EVENTS

5.1 DEFINITIONS

There are no adverse events anticipated form the taking of physical body measurements.

5.2 REPORTING PROCEDURES

All adverse events, if ever they should arise, although non anticipated, will be reported.

5.2.1 Non serious AEs

These will be recorded.

5.2.2 Serious AEs

An SAE form should be completed and faxed to the Chief Investigator within 24 hours. However, relapse and death due to <condition>, and hospitalisations for elective treatment of a pre-existing condition do not need reporting as SAEs.

All SAEs should be reported to the <name of REC> where in the opinion of the Chief Investigator, the event was:

•'related', i.e. resulted from the administration of any of the research procedures; and

•'unexpected', i.e. an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator must also notify the Sponsor of all SAEs.

Local investigators should report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs

Email: zb20006@bristol.ac.uk attention Chimwemwe Miti

Please send SAE forms to: zb20006@bristol.ac.uk

Tel: 01517089988 (Mon to Fri 09.00 – 17.00)

6. ASSESSMENT AND FOLLOW-UP

No follow up will be made

7. STATISTICS AND DATA ANALYSIS

Sample size calculation has proceeded using an online calculator (2). With a confidence interval of 95%, population size of 56 million(England, 2018), standard deviation of 5%. This gives an ideal sample size of 385.

Data collected will be subjected to correlational mathematic analyses using 'R' software package for statistical analysis.

No formal statistician input is required for this which is within the academic expertise of the PhD student applicant.

8. REGULATORY ISSUES

8.1 ETHICS APPROVAL

The Chief Investigator has applied for approval from the Research Ethics Committee and Health Research Authority (HRA) approval. The study will be submitted to each proposed research site for Confirmation of Capacity and Capability. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants are free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

8.3 CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act. Each scan performed has a unique patient identifier and will be requisite to retrieve the scan images. However, this will be mapped to a pseudonymised code that won't immediately identify the patient's scan instance. To avoid 'losing' scan instances through incorrect patient identifiers, the patient's hospital number will additionally be noted. Each scan will be anonymised and once the abdominal wall depth has been measured and associated to the respective patient's physical measurement with the patient being identified through a code, we will no longer need the hospital number and will instead use the pseudonymised code. Data such as age, gender & ethnicity will also be collected and not shared to any party outside of the research group. This data will be stored in a password restricted university laptop and the measures in place to store data in a secure fashion will follow general data protection regulations. It will not be possible to identify individual participants from the data linked to the pseudonymised code and only the research personnel will have access to this data. Person identifiable data will not be required. The physical measurement data will be retained for 10 years and destroyed thereafter. It will be retained securely should it be required for future use.

8.4 INDEMNITY

There are no requirements for arrangements for extra indemnity cover. This owes to the fact that there are no significant risks posed to any participants or researchers in this study and also that Liverpool Women's Hospital NHS Foundation Trust has agreed to act as sponsor of this project.

8.5 SPONSOR

The Liverpool Women's NHS Foundation Trust will act as the Sponsor for this study.

8.6 FUNDING

CDT Digital Health are funding this study. No participant or investigator payments will be effected.

8.7 AUDITS

The study may be subject to inspection and audit by the Sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be coordinated through zb2006@bristol.a.cuk

10. END OF STUDY

Data linkage for all recruited participants

11. ARCHIVING

Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study.

12. PUBLICATION POLICY

The results of this study will be published in a peer reviewed journal

13. REFERENCES

1. Y. Afifi, A. Raza, M. Balogun, K. S. Khan, R. Holders, New nomogram for safe laparoscopic entry to reduce vascular injury. Journal of Obstetrics and Gynaecology 31, 69-72 (2011).

2. Qualtrics (2022) Sample size calculator & complete guide. in ACADEMIC EXPERIENCE, ed Qualtrics (Qualtrics, USA).

14. APPENDICES

14.1 Principal Investigator responsibilities

The PI will attend the initiation meeting (already done) and ensure all members of the trial team are familiarised in the protocol and its procedures, attend to recruit patients at the point of their radiology attendance, enter all physical measurement data in the secure data sheet and correspond these to the respective scan image of the patient from which the abdominal wall depth will be calculated. Furthermore the PI will disseminate important safety or trial related information to all stakeholders within their site where required, safety report any incidents (highly unlikely) within the timelines and complete all study documentation.

14.2 **Required documentation**

14.21 CV of the Chief Investigator Hermes Gadelha- Bloomfield attached in IRAS Project Form

14.22 **Metric measurements**

Units of measurements (metric)	
Waist circumference	cm
Weight	kg
Height	cm
Abdominal wall depth	cm

14.3 **Expected Side Effects**

None anticipated as the data to be obtained from patients is simply height, weight and waist circumference.

14.4 **Schedule of events Excel Table**

Radiology Study		**PI: Hermes Gadelha-Bloomfield**			**Study Short Name: Waist circumference as an estimator of abdominal wall depth**			
Schedule Of Events:								
Study Item, Service, or Activity	Screening	Imaging day	Scan Post Processing				**Comments**	**Footnotes**
Patient identification & selection with radiology appointments department	X							non-urgent imaging only
Inclusion / Exclusion Criteria	X							
Participant Information Sheet given & Consent Signed	X	X						
Physical Exam		X						*end of participant physical involvement in the study
Abdominal wall depth calculation			X					Weight, Height, Waist circumference at Screening visit.
End of Study on achievement of sample size								