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Training in Ultrasound to Determine gestational Age (TUDA)

Submission date
24/01/2020

Recruitment status
No longer recruiting

Registration date
16/04/2020

Overall study status
Stopped

Last Edited
04/02/2022

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The study is part of a large programme of work to prevent preterm birth and stillbirth, DIPLOMATIC.

This is an implementation study of a training package for midwives to accurately assess gestational age from ultrasound scan 'in the first 24+6 weeks of pregnancy. Training in Ultrasound to Determine gestational Age (TUDA) forms the initial part of Work Package 5 within the DIPLOMATIC Programme, a National Institute for Health Research funded global health research programme, which aims to identify optimal interventions for the prevention of preterm birth and stillbirth in Malawi and Zambia.

Prevention and treatment of preterm birth requires an accurate assessment of gestational age during pregnancy. This is best achieved through ultrasound scanning (USS) measurements prior to 24 weeks gestation. The World Health Organisation (WHO) endorses the use of one ultrasound scan before 24 weeks gestation for all pregnant women. Such a goal is currently unattainable in many Low and Middle-Income Countries (LMIC) due to lack of availability of trained staff and ultrasound machines.

This pilot study aims to provide an ultrasound training program to enable staff to reach competency in determining the gestational age, the number of fetuses and fetal viability in early pregnancy. The establishment of accurate pregnancy dating by ultrasound scan in the selected settings is in keeping with current WHO recommendations (WHO 2016). We anticipate this information will inform the roll-out of an effective training package in Malawi and potentially also in Zambia

Who can participate?
1. The pilot will involve 8- 12 individual staff trainees per two sites and 3 trainers. Midwives and Clinical officers will be identified through the District nursing officers and District Health officers and those self-motivated and willing to gain ultrasound skills will be asked to write personal statements that would be scrutinized by the study investigators. Eligible participants will be

notified then invited for training.
2. Around 120 (per training site) antenatal women will consent to be scanned by more than one trainee.

What does the study involve?
For trainees, there will be one week of training, using the program designed for the TUDA study, followed by a four-week supervised evaluation of training. During the evaluation, midwives across the two participating health centres will be supervised closely to ascertain how much ongoing support is required to incorporate the scans into their routine pregnancy care. Quesionnaires will be used to explore the midwives' views and experience of the training package.

For patients, trainee midwives will use an ultrasound scan to assess how far along in their pregnancy they are.

What are the possible benefits and risks of participating?
No risks are anticipated to either trainees or women participating in this study.

Trainees will learn basic ultrasound skills and in time may be asked to help teach this to other people.

It will be possible to determine accurately how far along in their pregnancy women who participate currently are and this can be helpful if problems develop and the baby needs to be delivered early. Women will also be compensated for their time and travel.

Where is the study run from?
The training of staff and recruitment of women will take place in Malawi Liverpool Wellcome Trust (Malawi) and Mzuzu Central Hospital (Malawi)

When is the study starting and how long is it expected to run for?
April 2018 to May 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr. Alex Viner, A.Viner@ed.ac.uk (UK)
Dr. Luis Gadama, lgadama@medcol.mw (Malawi)

Contact information

Type(s)
Public

Contact name
Dr Alexandra Viner

ORCID ID
https://orcid.org/0000-0002-7674-6402

Contact details

Room W1.01 QMRI
47 Little France Crescent
Edinburgh
United Kingdom
EH16 4TJ
+44 01312422693
A.Viner@ed.ac.uk

Type(s)
Scientific

Contact name
Dr Luis Gadama

ORCID ID
https://orcid.org/0000-0002-7164-6197

Contact details
University of Malawi College of Medicine
Blantyre
Malawi
Southern Region
+265 99 104 2320
lgadama@medcol.mw

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 2

Study information

Scientific Title
The evaluation and implementation of a training package teaching ultrasound-naive midwives to become competent in establishing number of fetuses, fetal viability and gestational age prior to 24+6 weeks gestation

Acronym
TUDA

Study objectives
To evaluate the optimum methodology and minimum duration of training for ultrasound naive midwives to develop competency in performing scans to establish number of fetuses, fetal viability and determine gestational age under 24+6 weeks gestation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2019, University of Malawi College of Medicine Research and Ethics Committee (COMREC, College of Medicine, P Bag 360, Blantyre), ref: P.06/19/2714

Study design
This is a mixed-methods pilot study

Primary study design
Interventional

Study type(s)
Other

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

Interventions
8 to 12 health care workers from each of the participating centres will be trained over a period of one week using a bespoke training package designed to teach ultrasound niece midwives to perform ultrasound scans in the first 24 weeks of pregnancy to establish number of fetuses, fetal viability and determine gestational age using either crown-rump length or femur length measurements.

This will include classroom and clinical training. They will go for 4 weeks of mentorship at their respective facilities and their ultrasound competencies will be assessed. Ongoing competency will be based on the review of images and measurements sent from the midwives during the subsequent 4 week supervisory period. Continued support is also offered for a period of up to 6 weeks or longer if required. A small number will be invited to complete an interview about their experience of the training.

240 pregnant women will be recruited and will receive up to 4 fetal ultrasound scans in one day from trainees to determine accurately how far in pregnancy they are.

Intervention Type
Other

Primary outcome(s)
Gestation using measurement of either crown-rump length or femur length as compared with the trainers' results, through observation of the trainees' global clinical skills and through ongoing assessment of the trainees' images during the subsequent supervisory phase

Key secondary outcome(s))
1. To identify the experiential learning requirements which must be met after formal training to facilitate independent practice over a four week period. Trainee competency will be based on the achievement of 5 consecutive measurements that are within 10% of those obtained by the trainers and a global assessment from the trainers as to whether they deem the candidate ready based on observation of their performance. If they are not competent at the end of the week

competency will be assessed based on review of their submitted images during the supervisory phase.
2. To evaluate whether femur length measurements alone are adequate to assess fetal gestation in the study population using ultrasound scan assessed by comparing the estimated due date determined by the trainers' 3 femur length measurements to the estimated due date given by the trainers' composite measurements of head circumference, abdominal circumference and femur length
3. To explore the midwives’ views and experience of the training package using questionnaires and interviews to discuss their confidence in performing scans independently at the end of the 4 weeks mentorship.

Completion date
31/05/2021

Reason abandoned (if study stopped)
The planned follow up period was not possible due to the significant impact of the COVID-19 pandemic

Eligibility

Key inclusion criteria
1. Patients who are:
a. Pregnant
b. Estimated age ≥ 18 years
c. Signed (and witnessed, if applicable) informed consent given
2. Trainees who are:
a. Self-motivated midwives registered by the nurses and midwives council of Malawi and Clinical officers registered by the Medical Council of Malawi
b. Informed consent given

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
111

Key exclusion criteria

≥ 26 weeks' gestation based on clinical assessment prior to recruitment (note, where the trainer's femur length measurement subsequently suggests that the pregnant woman is more than 24+6 weeks' gestation the data will be discarded)

Date of first enrolment
20/01/2020

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
Malawi

Study participating centre
Malawi Liverpool Wellcome Trust
Queen Elizabeth Central Hospital
College of Medicine
PO Box 30096
Chichiri
Blantyre
Malawi
n/a

Study participating centre
Mzuzu Central Hospital
Private Bag 209
Mzuzu
Malawi
n/a

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes