Protocol for the e-POWUS Project: multicentre blinded-randomised controlled trial of ultrasound speed choice to improve sonography quality in pregnant women with obesity

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ABSTRACT

Introduction During pregnancy, maternal obesity increases the risk of fetal abnormalities. Despite advances in ultrasound imaging, the assessment of fetal anatomy is less thorough among these women. Currently, the construction of ultrasound images uses a conventional ultrasound propagation velocity (1540 m/s), which does not correspond to the slower speed of propagation in fat tissue.

The main objective of this randomised study is to compare the completeness of fetal ultrasonography according to whether the operator could choose the ultrasound velocity (1420, 1480 or 1540 m/s) or was required to apply the 1540 m/s velocity.

Methods and analysis This randomised trial is an impact study to compare a diagnostic innovation with the reference technique. The trial inclusion criteria require that a pregnant woman with obesity be undergoing a fetal morphology examination by ultrasound from 20^{+0} to 25^{+0} gestational weeks.

Randomisation will allocate women into two groups. The first will be the 'modulable speed' group, in which operators can choose the speed of ultrasound propagation to be considered for the morphological analysis: 1420, 1480 or 1540 m/s. In the second 'conventional speed' group, operators will perform the morphological examination with the ultrasound speed fixed at 1540 m/s. The adjudication committee, two independent experts, will validate the completeness of each examination and the quality of the images.

Ethics and dissemination This research protocol does not change the standard management. The only possible impact is an improvement of the ultrasound examination by improving the quality of the image and the completeness of morphological examination. The *Agence du Médicament et produits de santé* approved this study (2018-A03478-47). The anonymised data will be available on request from the principal investigator. Results will be reported in peer-reviewed journals and at scientific meetings.

Trial registration number ClinicalTrials.gov (http://www.clinicaltrials.gov) Registry (NCT04212234).

Strengths and limitations of this study

- ► It is the first randomised study offering sonographers a choice in the ultrasound velocity to be used for image construction of morphology scans in pregnant women with obesity.
- ► The sonographic quality will be evaluated by two experts, independent of the investigators, blinded to the propagation velocity and other patient data.
- ► The method of performing the ultrasound examination is reproducible in daily practice.
- ► The primary objective is completeness of the ultrasound examination, which enables the objective assessment of a clear-cut and clinically useful goal.
- ► The scoring of the sonography quality is subjective.
- ► The sequence for performing the ultrasound examination in pregnant woman is specifically adapted to French guidelines.

INTRODUCTION

The increased incidence of obesity is a major health problem that affects all age groups and all social levels, including women of childbearing age.[1 2]

While obese women are at greater risk of fetal abnormalities,[3–7] the performance of fetal morphological examination is less thorough despite advances in ultrasound imaging[8] and the performance of repeated examinations.[9–13]

To construct an image with ultrasound, the equations used the value of the propagation velocity of sound waves. In the human body, this velocity is considered conventionally to be constant and equal to 1540 m/s, and all manufacturers of ultrasound scanners have used this value since 1977.[14–18] Nevertheless, the real propagation velocity of ultrasound in fatty tissue is only on the order of 1450 m/s.[17] The quality of ultrasound images constructed

by the ultrasound software depends on insonation depth, energy absorption and dispersion of the ultrasound beam,[8] as well as on the distance–duration relation, according to the equation Z=cT/2 (where Z=depth, c=velocity of ultrasound propagation in a homogeneous medium and T=duration of the round trip of the wave between its source and target). Construction of an image by the scanner based on the conventional velocity of 1540 m/s when the actual velocity of propagation in the tissue studied is slower therefore produces discrepancies in the distances measured, with the reconstructed image of the target represented at a site and scale different from reality.[19] Speckling is increased, and lateral resolution and contrast are poor, so that a punctate object appears as a segment ('moustache effect').[19] The choice of a velocity of 1450 m/s for the construction of the image in the presence of fat to improve the image quality was initially suggested in mammary imaging, as the breast is a predominantly adipose organ.[19 20] To consider the slower sound wave velocity in fat tissue than in other soft tissues (ie, 1450 m/s vs 1540 m/s) for image construction should lead to better intrinsic image quality in terms of sharpness and precision.[21] The main objective of this randomised study is to compare the completeness of fetal ultrasound examinations according to whether the operator could choose to calculate sound wave velocity at 1420, 1480 or 1540 m/s or was required to apply the 1540 m/s velocity.

METHODS AND ANALYSIS

Study design

This blinded-randomised superiority trial is an impact study to compare a diagnostic innovation with the reference technique (figure 1).

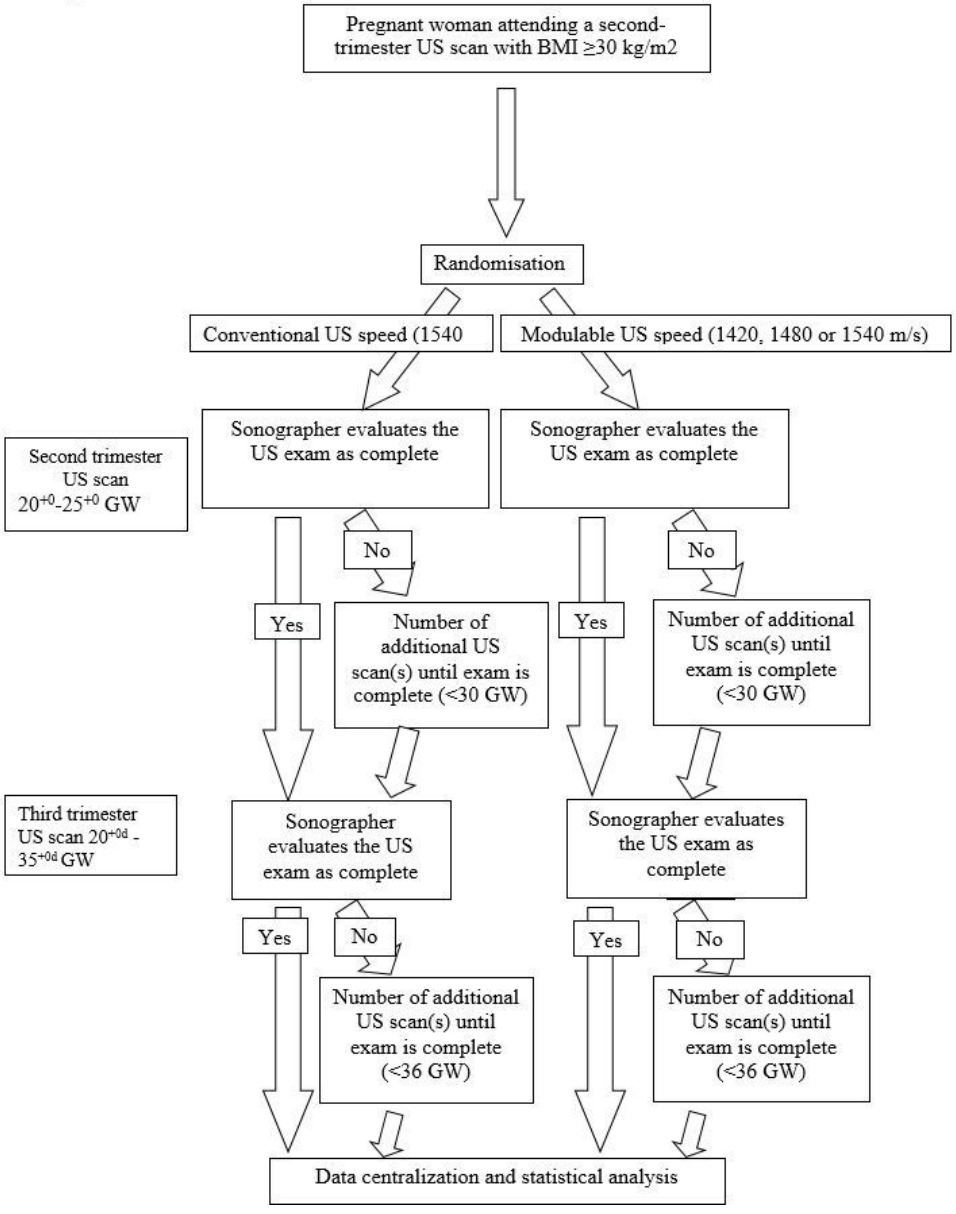

Figure 1 Study design. BMI, body mass index; GW, gestational weeks; US, ultrasound.

Study population

The trial inclusion criteria require that only pregnant women with obesity who are undergoing a fetal morphology examination by ultrasound from 20^{+0} to 25^{+0} gestational weeks (GW) be included.

The exclusion criteria cover any woman who:

- Refuses to have the ultrasound examination or to participate in the study.
- Is a minor or under guardianship/curatorship.
- Has an uncertain or unknown date of conception.
- Had a prepregnancy body mass index (BMI) <30 kg/m².
- Has a fetus with a congenital malformation or an anomaly of the amniotic fluid or the placenta, identified by an ultrasound scan earlier in this pregnancy ($<20^{+0}$ GW).
- Is carrying a multiple pregnancy.
- Has a scar of the abdominal, pelvic or uterine wall.
- Has a fibromatous uterus.

The woman's results will not be analysed if the fetus:

- Is diagnosed with a congenital anomaly during the study.
- Dies in utero during the study.
- Is diagnosed with an anomaly of the amniotic fluid or the placenta during the study.
- Is diagnosed as 'small for gestational age' (<10th percentile of estimated weight for gestational age on the curve of the French college of fetal ultrasound).

Study protocol

Version: 7.0 as of 24 May 2019.

Recruitment

Women may be recruited if their prepregnancy BMI ≥30 kg/m^2 and they are consulting for a second trimester fetal ultrasound examination in one of the study centres. All operators are experienced fetal ultrasonographers and practise in one of the French university hospitals listed below:

- University Hospital Estaing of Clermont-Ferrand.
- Maternity Port-Royal, Cochin hospital group of Paris.
- Croix-Rousse Hospital of the Hospices Civiles of Lyon.
- Woman-Mother Child Hospital of the Hospices Civiles of Lyon.
- University Hospital Arnaud de Villeneuve of Montpellier.

Intervention

Ultrasound monitoring of pregnancy in France includes three fetal screening examinations, one in each trimester. This examination is considered complete when all the views recommended by the French National Conference of Obstetric and Fetal Ultrasound (CNEOF) have been acquired (figure 2).

When the second trimester ultrasound is performed (between 20^{+0} and 25^{+0} GW), and if the woman meets the inclusion criteria, she will be randomised for the total duration of the study (figure 3). Thus, women will be allocated by randomisation to one of two groups:

- A first 'modulable speed' group in which operators may choose to have the image constructed by the scanner apply any of three sound wave propagation speeds (1420, 1480 or 1540 m/s) for the morphological analysis.
- A second 'conventional speed' group in which the only sound wave speed used to construct the images for the morphological examination is the conventional speed of 1540 m/s.

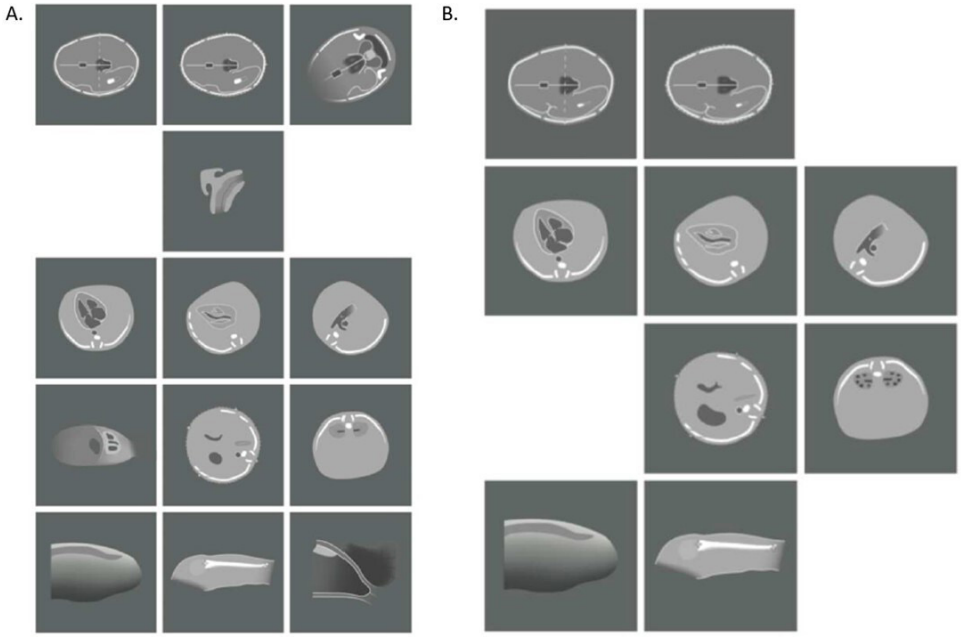

Figure 2 The ultrasound images recommended by CNEOF (A) for the second trimester ultrasound examination; (B) for the third trimester ultrasound examination. CNEOF, French National Conference of Obstetric and Fetal Ultrasound.

	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					Close-out
TIMEPOINT	*-t1*	0	*t1 Second-trimester ultrasound*	*t1' Completion of the second-trimester ultrasound*	*t2 Third-trimester ultrasound*	*t2' Completion of the third trimester ultrasound*	*t3 Birth*	*t4*
ENROLMENT								
Eligibility screen	X							
Informed consent	X							
Allocation		X						
INTERVENTIONS:								
Free choice of ultrasound speed			◆—	—	—	—◆		
Standard fixed-speed ultrasound technique			◆—	—	—	—◆		
ASSESSMENTS								
Completeness of the ultrasound scan			X		X			X
Comparison of the initial completeness assessed by the sonographer with that of the adjudication committee			X		X			X
Number of additional ultrasound appointments required for completeness of the standard examinations				X		X		X
Time stamping of each image and cumulative duration of all ultrasound examinations			X	X	X	X		X
Ultrasound speed used for each image			X	X	X	X		X
Strategies deployed by sonographers to improve the conditions of the ultrasound examination			X	X	X	X		X
Standardised measurements of adipose tissue thickness and probe-amniotic fluid distance			X	X	X	X		X
Position of the fetus and placenta			X	X	X	X		X
Incremental cost-effectiveness ratio								X

Figure 3 Time schedule of participant enrolment, interventions and visits.

During this examination, the morphological analysis of the fetus will be performed according to the standardised sections recommended by national and international guidelines.[22–24] The duration of each examination will be recorded and evaluated by the time elapsed between the first and last recorded image.

For each inclusion, the following data will be collected: for the mother, year of birth, geographical origin, number of pregnancies, parity, BMI and date of initiation of pregnancy; and for the operator, the number of years of practice.

For each ultrasound examination, the following data will be collected:

- Woman's weight on that day.
- Gestational age.
- Application of a cosmetic product in the preceding 48 hours.
- Patient's position at the start of the examination.
- Standardised measurements with the probe midway between the umbilicus and the pubis, performed only during the first ultrasound examination of the second and of the third trimester (figure 4):
  - Adipose tissue thickness (ATT): distance between the probe and muscle fascia.
  - Distance between the probe and amniotic fluid (PAF).
- Fetal and placental positions.
- Amount of amniotic fluid.
- Organ-specific scanning plane (ssp) measurements for each image recommended by the CNEOF (figure 4):
  - ssp-ATT.
  - Distance between the probe and the target organ.
- Completeness of acquisition of each image recommended by the CNEOF.
- Ultrasound speed used for each image.
- Need to change the maternal position (lateral decubitus, right or left).
- Need to use the vaginal probe in the umbilicus or vagina.
- Presence or absence of fetal anomaly.
- Completeness of the examination, evaluated by the operator.
- Cost of the examination, from the point of view of the French health insurance fund.
- Examination time.

When the second trimester ultrasound examination is considered complete, the pregnant woman will be seen by the same operator for the third trimester scan (between 30^{+0} and 35^{+0} GW), as described below. If it is not considered complete, the woman will be asked to return to repeat it as many times as necessary until it is complete, always with the same operator.

During the standard third trimester ultrasound scan between 30^{+0} and 35^{+0} GW, the images recommended by CNEOF must be acquired by the same sonographer as during the second trimester scan, with the same data

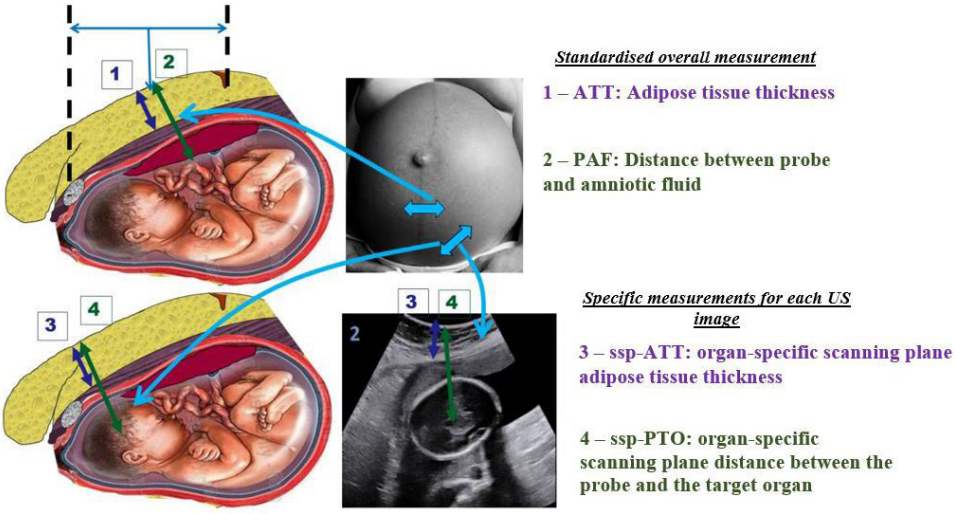

Figure 4 Standardised measurements taken halfway between the umbilicus and the pubis, performed during the first ultrasound (US) appointment of the second and of the third trimester: adipose tissue thickness (ATT)—distance between probe and muscle fascia; distance between probe and amniotic fluid (PAF). Organ-specific measurements for each ultrasound image recommended by the CNEOF: organ-specific scanning plane (ssp) ATT; ssp distance between the probe and the target organ (PTO). CNEOF, French National Conference of Obstetric and Fetal Ultrasound.

collected for each of the specific third trimester images recommended by the CNEOF. Similarly, in the event of incompleteness, the women will be asked to return for completion, but not after 36^{+6} GW.

In both randomisation groups, fetal biometrics will be measured exclusively at an ultrasound speed of 1540 m/s and according to CNEOF criteria since no reference curve has yet been developed for biometric data obtained at sound wave speeds other than 1540 m/s. Standardised abdominal wall thickness measurements (ATT and PAF) will also be performed at a sound wave speed of 1540 m/s.

The scanner used will be the Supersonic Imagine, Model AIXPLORER with a CE marking for obstetrics. It will be used with an abdominal curvilinear probe of 1–6 MHz. Each sonographer can choose all other ultrasound settings according to their personal preference.

Data will be collected about the birth (date and mode of delivery) and the child's status at birth (vital status, weight, height, head circumference and presence of a congenital malformation).

The case report forms will be completed electronically with Clinsight randomisation software.

Randomisation, patient allocation and blinding

The patients will be allocated into one of the two parallel arms by randomisation by blocks of four to balance the number of parturients in each arm. Because ultrasound is an operator-dependent examination, randomisation will be stratified by the sonographer to limit this operator effect: each sonographer will examine the same number of women in each arm. Women will thus be randomised not only to the study arm but also to the sonographer, so that their follow-up ultrasound will be performed by the same operator throughout the pregnancy.

Women will be masked to their allocation group in this study. The operators will run the ultrasound device programme according to the randomisation arm and must necessarily know if the programme allows speed modulation or not, since they will be able to use this option to optimise the subjective quality of the ultrasound images.

The standardised fetal planes produced during each scan will be exported in an anonymised form to a sharing platform for this study (Tricefy), with the acquisition speed of each plane deleted. Two experts, independently of the investigators and of each other, will validate the completeness of the first ultrasound examination at each trimester and the anatomical quality of the images (compliance with CNEOF recommendations) by applying the Salomon score criteria,[25] adapted to the CNEOF recommendations (tables 1 and 2). They will be blinded to the image acquisition speed. Their assessments will be entered in Clinsight by using the patient's participation number. The experts will not have access to the collected ultrasound examinations.

Objectives

Primary objective

Among women with obesity undergoing ultrasound examinations in the second and third trimesters of pregnancy, we seek to evaluate the effect on examination completeness of the operator's ability to choose the sound wave propagation speed (1420, 1480 or 1540 m/s), compared with completeness with the standard fixed-speed ultrasound technique (1540 m/s).

Secondary objectives

- Evaluate the accuracy of the assessment of 'examination completeness' assessed by an ultrasound operator in current practice.
- Describe in detail the procedures for performing the additional ultrasound examinations at the subsequent

Table 1 Salomon score adapted to the CNEOF recommendations for the second trimester fetal ultrasound

Biometric criteria			Morphological pictures									
Head circumference	**Abdominal circumference**	**Femoral length**	**Cranial box and its contents**	**Posterior cranial fossa**	**Face**	**4-chamber**	**Right outflow tract**	**Left outflow tract**	**Stomach/ diaphragm**	**Kidneys**	Spine	**Placental insertion**
Symmetrical planning	Symmetrical planning	Clear visualisation of both ends of the femur	Plane showing the thalami	Symmetrical cerebellar hemispheres	Upper lib visible	4 chambers visible	Pulmonary artery bifurcation visible	Aortic valve visible	Heart visible	Circular view of the first kidney	Dorsal spine visible	Maternal bladder visible
Plane showing the thalami	Plane showing the stomach bubble	Angle less than 45° from the horizontal	Plane showing the cavum of the septum pellucidum	Visible cerebellar vermis	Two nostrils visible	Apex of the heart visible	Ascending aorta visible	Ascending aorta visible	Stomach visible	Circular view of the second kidney	Sacrum visible	Internal os of the uterine cervix visible
Plane showing the cavum of the septum pellucidum	Plane showing the sinus door		Cerebellum not visible	Cisterna magna visible	Two lip angles visible	Heart crux visible	Right ventricle visible	Left ventricle visible	Spine non-visible	Posterior kidney clear from the spine acoustic shadow	Alignment of the vertebrae visible from the dorsal level to the sacrum	
Cerebellum not visible	Kidney not visible		Lateral ventricle visible			One pulmonary vein visible	Pulmonary artery curlicue up the aorta	Pulmonary artery curlicue up the aorta	Diaphragmatic interface visible from back to front	Corticomedullary differentiation or pyelic cavity visible	Continuity of the skin line	
Callipers and ellipse points correctly placed	Callipers and ellipse points correctly placed	Callipers and ellipse points correctly placed	Sylvian fissure visible			Descending thoracic aorta visible			Thigh and neck visible		Amniotic fluid visible beyond the skin	
Head occupying more than half of the total image size	Abdomen occupying more than half of the total image size	Femoral plane occupying more than half of the total image size	Head occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	

CNEOF, French National Conference of Obstetric and Fetal Ultrasound.

Table 2 Salomon score adapted to the third trimester fetal ultrasound

Biometric criteria			Morphological pictures					
Head circumference	**Abdominal circumference**	**Femoral length**	**Cranial box and its contents**	**4-chamber**	**Right outflow tract**	**Left outflow tract**	**Kidneys**	**Spine**
Symmetrical planning	Symmetrical planning	Clear visualisation of both ends of the femur	Plane showing the thalami	4 chambers visible	Pulmonary artery bifurcation visible	Aortic valve visible	Circular view of the first kidney	Dorsal spine visible
Plane showing the thalami	Plane showing the stomach bubble	Angle less than 45° from the horizontal	Plane showing the cavum of the septum pellucidum	Apex of the heart visible	Ascending aorta visible	Ascending aorta visible	Circular view of the second kidney	Sacrum visible
Plane showing the cavum of the septum pellucidum	Plane showing the sinus door		Cerebellum not visible	Heart crux visible	Right ventricle visible	Left ventricle visible	Posterior kidney clear from the spine acoustic shadow	Alignment of the vertebrae visible from the dorsal level to the sacrum
Cerebellum not visible	Kidney not visible		Lateral ventricle visible	One pulmonary vein visible	Pulmonary artery curlicue up the aorta	Pulmonary artery curlicue up the aorta	Corticomedullary differentiation or renal pelvic cavity visible	Continuity of the skin line
Callipers and ellipse points correctly placed	Callipers and ellipse points correctly placed	Callipers and ellipse points correctly placed	Sylvian fissure visible	Descending thoracic aorta visible				Amniotic fluid visible beyond the skin
Head occupying more than half of the total image size	Abdomen occupying more than half of the total image size	Femoral plane occupying more than half of the total image size	Head occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size	Region of interest occupying more than half of the total image size

appointments necessary to complete the two standard examinations in both groups.
- Identify possible strategies sonographers can deploy to improve the conditions of the ultrasound examination.
- Evaluate the economic impact, from both the hospital and health insurance perspectives, of modifying the parameter 'sound wave tissue propagation speed' to improve ultrasound performance in pregnant women with obesity.

Study endpoints

Primary outcome

The completeness of the ultrasound scan is the primary outcome. It will be derived from the two experts' assessments of each standard ultrasound for antenatal monitoring (the first appointment at or after 20^{+0} GW and the first at or after 30^{+0} GW) in both groups. This completeness will be established by the independent reading of the ultrasound images by the two experts, masked to both the other's judgement and the randomisation group. An examination will be considered complete by the adjudication committee if all of the images recommended by the CNEOF are acquired.[26] The initial concordance between experts will be quantified and any discrepancies will be resolved consensually.

Secondary outcomes

- Compare the initial completeness assessed by the sonographer with that of the adjudication committee.
- Number of additional ultrasound appointments required for completeness of the standard second and third trimester examinations.
- Time stamping of each image and cumulative duration of all ultrasound examinations.
- Ultrasound speeds used for each image.
- Strategies deployed by sonographers to improve the ultrasound examination (maternal position, probes, etc).
- Standardised measurements of ATT and PAF distance.
- Position of the fetus and placenta.
- For economic analysis: incremental cost-effectiveness ratio (ICER).

Patient and public involvement

The research protocol does not modify standard management; there is no need to prohibit participation in other research or to apply an exclusion period. Neither patients nor sonographers receive any compensation. This is indeed a routine examination.

Sample size calculation

Sample size was calculated based on the completeness rate of second trimester ultrasound scans estimated by Fuchs *et al*[11] (70.4%). With an assumed completion ratio of 80% in the intervention group (ie, modulable speed), a minimum calculated sample size of 640 would be required to receive a power level of 90% with an α of 5%. The statistical software used was SAS software (V.9.4; SAS Institute).

Statistical analysis

A κ coefficient will be calculated to evaluate inter-rater agreement between the two experts on the adjudication committee.

The statistical test will be one tailed for the main outcome.

The first step will be a univariate analysis. The completeness of the ultrasound examination at each time point will be compared between the two groups with a X^2 or Fisher's exact test.

The multivariable analysis will be conducted with a general linear mixed model. Group and gestational age at ultrasound examination will be included as fixed factors. The Tukey-Kramer method will be used to evaluate interaction between these two factors; if it is positive for interaction, the analysis will be stratified by group. Sonographers will be included in the analysis as a random effect, given that the ultrasound examination is sonographer dependent.

To evaluate the operators' assessment of the completeness of the examination, we will calculate sensitivity, specificity, and positive and negative predictive values, using completeness assessed by the adjudication committee as the reference.

The strategies sonographers used to improve the conditions for the ultrasound examination will be compared between the two groups for each scanning plane. Univariate analysis will use the X^2 or Fisher's exact test for categorical variables and the Student's t-test or Mann-Whitney test for continuous variables. Multivariable analysis will be performed with logistic regression or linear models. Sonographers will be included in the model as a random effect.

The analysis will be performed according to intention to treat.

Statistical analyses will be performed with SAS software (V.9.4).

Economic analysis

Two perspectives will be adopted for the economic analysis—that of the hospital and that of the health insurance fund. The duration of the examination and the procedures coded will be compared in the intervention and control groups to determine the cost-effectiveness of the two types of measures (conventional vs modular/optimal velocity).

From the hospitals' point of view, the direct medical costs will be taken into account, calculated by microcosting from the number and duration of examinations. Time spent by the sonographers will be valued by their hourly salary to calculate the gains or opportunity costs. We will conduct a sensitivity analysis that incorporates different assumptions for scanner depreciation costs, according to the material acquisition possibilities and commercial sales policies. The effectiveness will be

measured by the completeness of the examination during the first ultrasound appointment in the second and the third trimesters. The ICER will be calculated and a cost-efficiency plan will be used to present the results.

From the health insurance point of view, the costs considered will be the reimbursed costs at the conventional (official basis for reimbursement) prices, depending on the number and type of ultrasound examinations performed. The efficiency criterion will also be the completeness of the examination during the first ultrasound appointment of the second and the third trimesters.

Data Monitoring Safety Committee

The only possible impact (and the subject of the study) is an improvement in the ultrasound examination and its efficiency by improving the quality of the image to increase the likelihood of a complete scan at the first appointment in both the second and third trimesters.

French law and regulations do not require a Data Monitoring Safety Committee for human research involving minimal risks and constraints. Rather, the law and reporting required for routine care, standard health surveillance and pharmacovigilance apply to this type of study.

Data storage and management

The case report forms will be completed electronically with the Clinsight randomisation software, verified locally in each centre by the sonographer and a clinical research associate, and then centralised by the primary investigation centre. Centralised quality control will also take place. It will be carried out by a clinical research assistant from the trial sponsor. This control will take place according to the following plan: a first early visit will take place in each centre after five inclusions then every 6 months according to the rate of inclusions.

During the study, the data collected from individuals included in the study and transmitted to the project sponsor by investigators or the clinical research associate shall be anonymised. Under no circumstances will they disclose the names or addresses of the persons concerned.

An inclusion number will be assigned to each patient included by the Clinsight software. The images will be anonymised during their loading onto the Tricefy platform. Only the patient's inclusion number will be visible on images there; it will serve as the key to the result of the expert assessment. Only the experts on the adjudication committee will have access to the ultrasound images on the platform, and this access is personal and temporary for the duration of the study.

The sponsor shall ensure that each person who is included in the study has given her written consent to access the individual data concerning her that are necessary for quality control.

The project sponsor is responsible for obtaining the agreement of all parties involved in the research to ensure direct access to all research sites, source data, source documents and reports for the purpose of quality control and audit by the sponsor. Investigators shall make available the documents and individual data necessary for the monitoring, quality control and audit of research involving human subjects to persons authorised to have access to these documents in accordance with the laws and regulations in force in France.

The case report forms completed during this study will be kept for 15 years by the principal investigator, within the Public Health Department of the University Hospital of Clermont-Ferrand.

Ethics and dissemination

The first patient inclusion was on 2 December 2019, and we hope to recruit 128 patients in each centre for a total of 640 within 24 months of the first recruitment.

Patients will be informed in a complete and fair manner of the objectives and constraints of the study, the possible risks involved, the necessary surveillance and safety measures, their right to refuse to participate and the possibility of withdrawing at any time. The investigator will obtain the free, informed and written consent of the patient before including her in the study.

The investigator undertakes to conduct this study in accordance with Good Clinical Practices and the public health law in force in France. The protocol complies with the Declaration of Helsinki. The number of ethics committee approval for this study is 2018-A03478-47, approved by the independent Protection of Persons Committee number 19.05.09. This multicentre, randomised, parallel-group trial is registered at http://www.clinicaltrials.gov. All significant changes to the protocol will be validated by this committee and will be documented at http://wwwclinicaltrialsgov.

The anonymised data will be available on request from the principal investigator. The data collected will be centralised and stored on a server at the study coordinating centre (Clermont-Ferrand), where they will be extracted, analysed and used. The data will be divulged only after the joint accord of the principal investigator and the sponsor. The results will be the subject of scientific communications and publications. Authorship eligibility will follow the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, 2015.

DISCUSSION

Several studies have shown that it is currently difficult to obtain complete and good quality fetal ultrasound examinations in pregnant women with obesity.[11 27]

In a preliminary study (POWUS), we showed that considering the parameter of sound wave tissue propagation speed, which is slower in fatty tissue, made it possible to improve the constitutive image of four planes of standardised anatomical fetal sections in the second trimester of pregnancy in women with a preconceptional BMI >30. Experts with extensive experience in ultrasound examinations were asked to rate the quality of the images obtained

by applying either a 'slow' (1480–1420 m/s) or 'standard' (1540 m/s) sound wave speed for the construction of the images obtained in these patients. They showed a significant preference for the images obtained with the slower ultrasound speed.[21 28]

No study has yet evaluated the impact, in this ever-growing obese population, of this new machine adjustment parameter on the efficiency of ultrasound monitoring of pregnancy in terms both of the ability to perform a complete fetal morphological screening and of the duration or repetition of the ultrasound examinations necessary to complete it.

Our main hypothesis is that the use of variable speed ultrasound will produce more complete initial examinations than the standard-speed ultrasound examinations of pregnant women with obesity. We aimed to reach the same completeness for obese women in the intervention group as that obtained in other studies for women who are not obese. Several studies have demonstrated that the feasibility of a complete scan is 57%–70% in obese groups and 70%–80% in non-obese groups.[11 28] Sample size was evaluated based on the upper range of completeness in both groups, given that those proportions come from a French centre and reflect the performance of French ultrasonographers. Nonetheless, this sample size is available only for second trimester ultrasounds; to our knowledge, no study has evaluated completeness at the third trimester. Our secondary hypothesis is that ultrasound operators consider the examination to be complete even if the image quality is not always fully satisfactory in this difficult situation. Other strategies might also help to improve the quality of ultrasound examinations. The use of variable speed ultrasound should reduce the number of additional ultrasound examinations and the economic impact of ultrasound performance in pregnant women with obesity.

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Contributors AD designed/wrote this protocol, conducted a previous study on this subject and is the principal investigator. BC designed/wrote this protocol and conducted a previous study on this subject. DL designed/wrote this protocol and conducted previous studies on this subject. AO was responsible for setting up and monitoring the study. CG-A performed the statistical analyses. CM performed the economic analyses. AL designed/wrote this protocol, conducted previous studies on this subject and supervised the statistical analyses.

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