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Validity of the third trimester ultrasound screening at 36 weeks compared to 32 weeks gestational foetus in the detection of small for gestational age

Submission date
15/04/2011

Recruitment status
No longer recruiting

Registration date
05/12/2011

Overall study status
Completed

Last Edited
05/12/2011

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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled clinical trial on the validity of the third trimester ultrasound screening at 36 weeks compared to 32 weeks gestational foetus in the detection of small for gestational age

Study objectives
The studies conducted so far on the impact of routine ultrasound in the third quarter results are uncertain. According to the Cochrane meta-analysis performed by the routine ultrasound performed beyond 24 weeks gestation does not provide benefits. We interpret the studies in the context in which they were designed. Most of them differ very much in the way we act today. In addition some studies do not change the action in the diagnosis of foetal growth restriction and have no impact on perinatal outcomes, other studies if they introduce more measures to control welfare and suggest that non-detection of growth retardation leads to greater mobility and mortality. The foetuses with growth restriction have an increased risk of perinatal complications, neonatal and during adulthood. What has not been identified even if it is more sensitive at 36 than at 32 weeks following the current guidelines on gestational control.

The sensitivity for detection of ultrasound foetus small for gestational age (FPEG) third quarter unselected population of pregnant women is 20% higher if they perform at 36 to 32 weeks of gestation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of the Union Catalan Foundation Hospitals approved on March 29th 2011

Study design
Randomised controlled parallel study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Small foetuses for gestational age and intrauterine growth restriction

Interventions
1. The third trimester ultrasound screening was carried out using randomisation. In the control group of pregnant women to take during the week 32 and in the case group during week 36, where static value it again foetal membranes ovulars, the foetal biometry and detection of foetal malformations, by using the calculation of weight Hadlock formula to calculate the corresponding percentile of growth.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Measurements of biparietal diameter (BPD), were obtained from a transverse axial plane of the foetal head showing a central mid-line echo broken in the anterior third by the cavum septii pellucidi and demonstrating the anterior and posterior horns of the lateral ventricles. BPD was measured from the outer borders of the skull. The hemisphere was measured from the mid-line to the inner border of the skull.
2. Chest circumference (CC) was measured in the same axial plane, outside the bone
3. The femur length (FL) was measured from the greater trochanter to the lateral condyle
4. For abdominal circumference (AC), a transverse section of the fetal abdomen was taken at the level of the stomach and the bifurcation of the main portal vein into its right and left branches
All the measurements were performed on two occasions, and avaerage was calculated. The same measurements were perfomed in the group of 32 weeks, and in the group of 36 weeks, similar.

Secondary outcome measures
1. The calculation of foetal weight is estimated using the formula of Hadlock 14. Formula BPD, PC, PA, LF. MA (age mesntrual) = 10.85 + 0.060 (PC) (LF) + 0.6700 (BPD) + 0.1680 (BP). With standart deviation of 1.02 and a maximum error of 3.2 weeks
2. The limitation of the percentile will follow the following outline or calculate the difference between the percentile of the week in particular and the upper (PE week 33 between the 20th percentile, 10th percentile and 34th the difference is 10), divide by the difference between 7 days in the week (10 / 7 = 1.4) and so will the change in percentile day. Apply the difference Percentile day (PE at 33, three would be 1.4 x 3 = 4.2 and therefore would be 20 to 4.2 = 15, 8)
The ultrasound used are:
2.1. Voluson 730 Expert.
2.2. Acuson Antares. Siemens.
2.3. Toshiba 20 Nemi

Overall study start date
01/05/2011

Completion date
01/05/2014

Eligibility

Key inclusion criteria
1. Age greater than or equal to 18 years
2. Gestation of single foetus
3. Gestation length cranes flow dated by LCC or the first quarter
3.1. No foetal malformations detected in the first or second quarter
3.2. Absence of pregestational diabetes, renal or autoimmune diseases, chronic hypertension
4. Sign the informed consent of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
2600

Key exclusion criteria
1. Have participated in a clinical research study during the last 3 months
2. Inability to sign informed consent or do not want to do it

Date of first enrolment
01/05/2011

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Spain

Study participating centre
Arquitecte Gaudí 94
Artes
Spain
08271

Sponsor information

Organisation
Hospital Sant Joan de Déu (Spain)

Sponsor details
c/o Dr. Joan Soler
s/n 08243 - Manresa
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Sponsor type
Not defined

Website
http: www.althaia.org

ROR
https://ror.org/001jx2139

Funder(s)

Funder type
Government

Funder Name
Althaia, Network Healthcare Manresa Foundation (Spain) (ref:G5828630)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration