Size and volume charts of fetal bladder during the second and third trimester of pregnancy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON42511

Source
ToetsingOnline

Brief title
FEBLA

Condition

- Renal and urinary tract disorders congenital
- Neonatal and perinatal conditions
- Bladder and bladder neck disorders (excl calculi)

Synonym
Lower urinary tract obstructions; Enlarged Fetal Bladder

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fetal Bladder Reference Charts, Fetal Megacystis, Lower Urinary Tract Obstructions, Prenatal Diagnosis

Outcome measures

Primary outcome

Main endpoint will concern the creation of reference charts for fetal bladder

dimension and volume in the second and third trimester of pregnancy.

Secondary outcome

Secondary endpoint will be the prospective validation of both reference charts

and prediction model designed by MEBLA study (NL54637.042.15) in 20 cases of

megacystis diagnosed in subsequent years

Study description

Background summary

An enlarged fetal bladder (megacystis) is a rather infrequent ultrasound finding related to a wide spectrum of causes. Although the most common cause is lower urinary tract obstructions (LUTOs), fetal megacystis is also associated with more complex congenital malformations or chromosomal and genetic anomalies, but it can also be a transitory finding, with eventually normal bladder size and renal function at birth. The mechanism leading to megacystis in LUTOs consists of a bladder neck obstruction caused by urethral atresia or posterior urethral valves resulting in progressive urine retention in the dilated fetal bladder. The natural history of LUTO is highly variable and it is associated with high perinatal mortality (45%) and postnatal morbidity. In light of variable etiology and outcome, the prenatal counseling of parents in case of fetal megacystis is particularly challenging.
Between the 10th and 14th week, the definition of enlarged bladder is clear and refers to a sagittal bladder diameter * 7 mm. Moreover, the measurement of the sagittal diameter during this period has been found of help to discriminate fetuses with chromosomal defects and those with LUTO.
On the contrary, after the 14th week the definition of megacystis is variable

and subjective. Most of the study considers as enlarged, a bladder with failure to empty in 45 minutes. This definition implies research bias and currently affects the reliability of the studies in literature. Furthermore, the absence of reference ranges makes it not possible staging the degree of the bladder enlargement and thus of the urinary obstruction, in order to properly manage the foetuses with LUTO and conscientiously counsel the parents.

Study objective

The main objective of the study is to construct reference curves for fetal bladder diameters and volume in the second and third trimester of pregnancy. Moreover we will investigate the variation in the dimensions of renal pelvis in relation to the degree of bladder filling in healthy fetuses compared to 20 cases with mild pielectasy (defined as an antero-posterior renal pelvis between 5 and 10 mm).
Secondary objective will be to prospectively validate both the cut-off of bladder enlargement derived from this study and the prediction model for postnatal renal function designed by MEBLA (NL54637.042.15) study, in 20 cases of megacystis diagnosed in subsequent years.

Study design

Cross-sectional study.

An ultrasound examination will be performed in a cohort of 300 pregnant women with healthy fetuses, repeating three ultrasound examinations, each lasting approximately 5 minutes at an interval of 20 minutes. All three examinations will take place during the same appointment. The measurements are non-invasive and not associated with any known risks for the pregnant woman or her fetus.

The measurements will be performed by 3D transabdominal ultrasonography:
A 3D sweep will be taken of te fetal bladder and stored digitally in the memory of the ultrasound equipment (Voluson E8 or Voluson E10, GE) . This lasts about 10 seconds.
On the sweep the following measurements will be performed
1) The fetal bladder longitudinal length (FBSL) obtained at the level of the midline sagittal plane. The distance from bladder dome to bladder neck will be collect in millimeters by placing the calipers on the inner borders of the bladder wall. After three measurements, the longest diameters will be collected.
2) Anteroposterior (AP) and transverse diameters will be measured from the largest transversal view by placing the calipers on the inner borders of the bladder wall.
3) Two measurements (anterior and posterior) of the bladder wall will be obtained at the level of pubic bone.
4) The bladder volume will be calculated by the off line buil-in function

SonoAVC (Sonography-based Automated Volume Count) .
5) On the same 3D volume both renal pelvis will be measured following the same method

Study burden and risks

Three Abdominal ultrasound examinations will be performed on the same day, each one will last 5 minutes. No physical, psychological examinations and neither particular diet or specific behavioural rules are required.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Physiological singleton pregnancy in healthy women aged 18 or older, carrying a fetus without structural anomalies and capable of reading the Dutch language will be recruited at the dating scan (10-14 weeks).
Moreover twenty cases referred to our Fetal Unit for mild pyelectasy, defined as an anteroposterior diameter of renal pelvis between 5-10 mm during pregnancy, will be included in the study.

Exclusion criteria

Exclusion criteria are: incapacitated adults, maternal disease that are likely to affect the fetal growth (hypertension requiring therapy, diabetes mellitus), multiple pregnancies, the presence of fetal anomalies, abnormal karyotype or any other disease at birth. Congenital abnormalities will be ruled out at the second trimester abnormality scan and / or after birth

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2016
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	26-04-2016

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23144
Source: NTR
Title:

In other registers

Register	ID
Other	Nederlands Trail register, pending number
CCMO	NL54636.042.15
OMON	NL-OMON23144