In utero sonographic assessment of calve muscles in fetuses with clubfeet (pes equinovares) and fetuses with no structural anomalies with follow-up after birth.

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Ethical review	Approved WMO
Status	Completed
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON48647

Source
ToetsingOnline

Brief title
In utero sonographic assesement of calve muscles in fetuses.

Condition

- Musculoskeletal and connective tissue disorders congenital
- Musculoskeletal and connective tissue disorders congenital
- Neonatal and perinatal conditions

Synonym
Clubfeet, Pes equinovares

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clubfeet, Foetus, Ultrasound

Outcome measures

Primary outcome

The primary objective of the study is to examine muscle atrophy in fetuses with single or bilateral PEV, in comparison to a normal population by measuring the circumference of the upper and lower legs. The measurements will be performed prenatally at 20 weeks of gestation and around 28-30 weeks of gestation, neonates will be examined directly after birth and 6 weeks post-partum.

Secondary outcome

The length of the bones of the upper- and lower extremities and the length of the feet will be measured to examine if there is a difference in the length of the bones in fetuses affected with single or bilateral IPEV in comparison to the normal population.

Study description

Background summary

Muscle- or central nervous system anomalies can induce muscle atrophy, causing weakness of the calves and bones deformities, this could contribute to the development of club feet (pes equinovares). We hypothesized that if this theory holds true the muscle atrophy may already be visualized prenatally by means of ultrasound examination in fetuses suspected of single or bilateral idiopathic

pes equinovares (IPEV) at the 20 week standard anomaly scan. We will compare these fetuses to a normal population without structural anomalies.

Study objective

The primary objective of the study is to examine muscle atrophy in fetuses with single or bilateral IPEV, in comparison to a normal population by measuring the circumference of the upper and lower legs by ultrasound examination.

The length of the bones of the upper- and lower extremities and the length of the feet will be measured in fetuses affected with single or bilateral IPEV, the measurements will be compared to a normal population.

Study design

This is a prospective cohort study.

Study burden and risks

The extra measurements will take an extra 5-10 minutes in addition to the standard anomaly scan or targeted ultrasound examination. The follow-up ultrasound examination at 28 weeks of gestation will be an additional ultrasound examination for the normal population, this is not harmful for the fetus nor the mother. Unless there was another indication for an ultrasound around 28 weeks (e.g. growth or placenta location). During this ultrasound examination the regular ultrasound examination including follow-up of the growth will be performed. The ultrasound will be combined with an appointment.

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

- Patient should be over the age of 18 years
- Singleton pregnancy
- All fetuses with unilateral or bilateral idiopathic pes equinovares referred to, or presenting at, Amsterdam UMC for targeted ultrasound examination around 20 weeks of gestation.

Exclusion criteria

- Patients under 18 years
- Twin pregnancy
- Multiple congenital anomalies
- An- or oligohydramnios
- History of uterus anomalies
- Septa in the uterine cavity during this pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-04-2020
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL66727.029.18