# The predictive value of fetal scalp lactate to negative neonatal outcomes

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

# **Summary**

## ID

NL-OMON22001

Source NTR

Brief title FBS-study

#### Health condition

Fetal blood sampling during labor due to a suspicion of fetal distress

# **Sponsors and support**

Primary sponsor: Máxima MC Source(s) of monetary or material Support: N/A

## Intervention

## **Outcome measures**

#### **Primary outcome**

Negative predictive value and positive predictive value of fetal scalp lactate on neonatal acidosis. Neonatal acidosis is associated with arterial umbilical cord pH <7.10 and base deficit >-12, Apgar scores <7 after 5 minutes and admission to the neonatal intensive care unit.

#### Secondary outcome

NPV and PPV of fetal scalp lactate on composite outcomes (defined as either arterial umbilical cord pH <7.10 and base deficit >-12 or Apgar scores <7 after 5 minutes or admission to the neonatal intensive care unit).

PPV and NPV of fetal scalp lactat on interventionrate

Discrepancies between fetal scalp lactate and fetal scalp pH measurements

Failure rates of fetal scalp lactate, fetal scalp pH and umbilical cord pH measurements CTG pattern at time of fetal blood sampling

Fetal scalp lactate pattern in case of repeated measurements

# **Study description**

#### **Background summary**

In this retrospective cohort study, we would like to determine the negative and positive predictive values of fetal scalp lactate measurements in case of non-reassuring heart rate patterns on adverse neonatal outcomes. In our cohortstudy, both fetal scalp pH and fetal scalp lactate measurements are sampled at the same time.

#### **Study objective**

Fetal scalp lactate measurement is equally good or superior than fetal scalp pH measurements during labor in case of nonreassuring fetal heart rate patterns in predicting adverse neonatal outcomes.

#### Study design

Start of study: 15-1-2020

#### Intervention

Fetal Blood sampling

# Contacts

#### Public

Máxima Medisch Centrum, Veldhoven Marion Frenken

040-8888380

2 - The predictive value of fetal scalp lactate to negative neonatal outcomes 11-05-2025

**Scientific** Máxima Medisch Centrum, Veldhoven Marion Frenken

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# **Eligibility criteria**

## **Inclusion criteria**

Women in labor with fetal blood sampling during labor Giving birth in our centre (Máxima MC) Singleton fetus Cephalic presentation

## **Exclusion criteria**

Maternale age <18 years old Gestational age <34+0 weeks Multiple pregnancy Suspicion of fetal clotting disorder Maternal infection like HIV or hepatitis

# Study design

## Design

Study type:Observational non invasiveIntervention model:OtherAllocation:Non controlled trialMasking:Open (masking not used)Control:N/A , unknown

#### Recruitment

NL Recruitment status:

Pending

Start date (anticipated):	15-01-2020
Enrollment:	1240
Туре:	Anticipated

## **IPD** sharing statement

Plan to share IPD: Undecided

# **Ethics review**

Positive opinion	
Date:	14-01-2020
Application type:	First submission

# **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
NTR-new	NL8305
Other	METC Máxima MC : N20.006

# **Study results**