Management of Fetal Growth Restriction at Term: Angiogenic Factors Versus Feto-placental Doppler

**CLINICALTRIALS.GOV IDENTIFIER**
NCT04502823

**RECRUITMENT STATUS**
RECRUITING

**FIRST POSTED**
AUGUST 6, 2020

**LAST UPDATE POSTED**
JANUARY 11, 2022

**STUDY DESCRIPTION**

**Brief Summary**

Open randomized non-inferiority controlled trial to examine the use of angiogenic factors (instead of feto-placental Doppler) for fetal growth restriction at term to reduce the rate of labor inductions, without worsening perinatal outcomes.

**Condition or Disease:** Fetal Growth Retardation

**Intervention/treatment:** Procedure: Management based on sFlt-1/PlGF values

**Phase:** Not Applicable

**DETAILED DESCRIPTION**

Pregnant women with estimated fetal weight (EFW) < 10th centile between 36+0 and 37+6 weeks of gestation (WG) will receive complete ultrasonographic assessment consisting of feto-placental Doppler, amniotic fluid measurement and biophysical profile assessment. The cases not meeting any exclusion criteria will be offered to participate in this trial. After giving their informed consent a blood sample will be drawn in all of them and they will undergo randomization into two arms. Intervention arm: In women allocated to the intervention group, the soluble fms-like tyrosine kinase/placental growth factor (sFlt-1/PlGF) result will be revealed to the investigators that will act according to the results of sFlt/PlGF: Fetuses with sFlt-1/PlGF ≥38, elective delivery will be recommended at ≥37 weeks. Fetuses with sFlt-1/PlGF <38, weekly follow up will be recommended until delivery (at ≥40 weeks). Control arm: In women allocated to the control group, the sFlt-1/PlGF result will be blinded to caregivers. Routine Doppler-based clinical care will be used to counsel women. Following the Doppler classification: Fetuses with EFW below the 3rd centile or below the 10th centile accompanied by any impaired fetoplacental Doppler, elective delivery will be recommended at ≥37 weeks. Fetuses with EFW above the 3rd centile without any fetoplacental Doppler abnormality, elective delivery will be recommended at ≥40 weeks. In both arms, fetuses will receive weekly follow-up from randomization to delivery consisting on feto-placental Doppler sFlt-1/PlGF and CTG. If any of the following is present at any time, earlier delivery will be recommended: sFlt-1/PlGF ≥38 (only in the intervention group), absent or reverse end-diastolic flow at the umbilical artery Doppler or DV PI >95th centile non-reassuring CTG preeclampsia diminished fetal movements biophysical profile ≤ 6 or oligohydramnios (deepest pocket <2 cm).

**STUDY DESIGN**

**Study Type:** Intervenional

**Estimated Enrollment:** 1030 participants

**Allocation:** Randomized

**Intervention Model:** Parallel Assignment

**Masking:** None (Open Label)

**Primary Purpose:** Treatment

**Official Title:** Management of Fetal Growth Restriction at Term: Angiogenic Factors Versus Feto-placental Doppler

**ARMS AND INTERVENTIONS**

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
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<tbody>
<tr>
<td>Experimental: Intervention Group Management based on sFlt-1/PlGF values</td>
<td>Procedure: Management based on sFlt-1/PlGF values. In women allocated to the intervention group, the sFlt-1/PlGF result will be revealed to the investigators that will act according to the results of sFlt/PlGF: Fetuses with sFlt-1/PlGF ≥38, elective delivery will be recommended immediately within 24h at ≥37 weeks. Fetuses with sFlt-1/PlGF &lt;38 weekly follow up will be recommended and delivery at ≥40 weeks.</td>
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**OUTCOME MEASURES**

**Primary Outcome Measures:** 1. Adverse perinatal outcomes [ Time Frame: 4-6 weeks ] Cesarean delivery for non-reassuring fetal status or neonatal acidosis (artery cord potential of hydrogen (pH) <7.15 + base excess >-12 milliequivalent/L)

**Secondary Outcome Measures:** 1. Rate of elective delivery [ Time Frame: 4-6 weeks ] Percentage of women that required an elective delivery 2. Rate of Cesarean delivery [ Time Frame: 4-6 weeks ] Percentage of women that required a Cesarean delivery 3. Rate of Induction of labor [ Time Frame: 4-6 weeks ] Percentage of women that required an induction of labor
4. Rate of neonatal admission in intensive care unit [Time Frame: 4-6 weeks]
Percentage of newborns that required admission in intensive care

5. Days in intensive care of newborns that required admission

6. Rate of preeclampsia [Time Frame: 4-6 weeks]
Percentage of women that developed preeclampsia

7. Rate of newborns with adverse outcomes [Time Frame: 4-10 weeks]
Percentage of newborns with adverse outcomes (composite)

8. Rate of maternal complications [Time Frame: 4-6 weeks]
Percentage of women with adverse outcomes (composite)

9. Rate of perinatal complications [Time Frame: 4-6 weeks]
Percentage of perinatal adverse outcomes (composite)

10. Rate of total deliveries at <37, <38, <39 and <40 weeks of gestation
Percentage of women that delivered at <37, <38, <39 and <40 weeks of gestation

11. Rate of elective deliveries at <37, <38, <39 and <40 weeks of gestation
Percentage of women that delivered electively at <37, <38, <39 and <40 weeks of gestation

12. Rate of newborns with birthweight <2000 and <2500 grams [Time Frame: 4-6 weeks]
Percentage of newborns that delivered a newborn with a birthweight <2000 and <2500 grams

ELIGIBILITY CRITERIA

Ages Eligible for Study: 16 Years and older (Child, Adult, Older Adult)

Sexes Eligible for Study: Female

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

CONTACTS AND LOCATIONS

Contacts
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Locations

Spain Hospital Universitario de A Coruña A Coruña
Spain Hospital General de Alicante Alicante
Spain Hospital Germans Trias i Pujol Badalona
Spain Hospital Universitari Vall d’hebron Barcelona
Spain Hospital Universitari de Cabueñes Cabueñes
Spain Hospital Universitario Puerta del Mar Cadiz
Spain Hospital General Universitario de Eliche Elche
Spain Hospital Universitario de Getafe Getafe
Spain Hospital Universitari Doctor Josep Trueta Girona
Spain Hospital Sant Joan de Deu de Manresa Manresa
Spain Hospital Clínico Universitario Virgen de la Arrixaca Murcia
Spain Hospital Son Llàtzer Palma De Mallorca
Spain Consorci Corporació Sanitària Parc Taulí de Sabadell Sabadell
Spain Hospital Universitario Nuestra Señora de Candelaria Santa Cruz De Tenerife
Spain Hospital Universitario Virgen de Valme Sevilla
Spain Hospital Universitari Joan XXIII Tarragona
Spain Hospital de Terrassa Terrassa
Spain Hospital Universitari Mútua Terrassa Terrassa
Spain Hospital Universitario de Torrejon Torrejón De Ardoz
Spain Hospital Clínico Universitario Lozano Blesa Zaragoza

Sponsors and Collaborators
Hospital Universitari Vall d’Hebron Research Institute

Investigator
**MORE INFORMATION**

**Responsible Party:** Hospital Universitari Vall d'Hebron Research Institute

**ClinicalTrials.gov Identifier:** NCT04502823

**Other Study ID Numbers:** PR(AMI)527/2019

**First Posted:** August 6, 2020

**Last Update Posted:** January 11, 2022

**Last Verified:** July 2021

**Studies a U.S. FDA-regulated Drug Product:** No

**Studies a U.S. FDA-regulated Device Product:** No

**Additional relevant MeSH terms:**
- Fetal Growth Retardation
- Fetal Diseases
- Pregnancy Complications
- Growth Disorders
- Pathologic Processes