### Project: Oxytocin Treatment in neonates and infants (BaBies) with Prader-Willi syndrome: effects of intranasal administrations of oxytocin in infants aged from 0-3 months vs. placebo on sucking and swallowing (phase III clinical trial) OTBB3-Trial

<table>
<thead>
<tr>
<th>Project: Objectives</th>
<th>Design &amp; Phase</th>
<th>Countries</th>
<th>No. of Patients</th>
<th>Investigational Medical Product (IMP)</th>
<th>Follow-up End points</th>
<th>Start Date</th>
<th>End Date</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTBB3 study</td>
<td>Phase 3</td>
<td>France, Germany, Belgium, Italy, Netherlands</td>
<td>52</td>
<td>Syntocinon: spray nasal (5ml; 40 UI/ml)</td>
<td>5 months Duration of the inclusion period: 18 M Duration of each patient's participation: 5 M Total duration of the study: 3 years</td>
<td>01/11/2017</td>
<td>01/11/2020</td>
<td>Is sucking/swallowing assessed after 1 month of treatment by the Neonatal Oral-Motor Assessment Scale (NOMAS) scored on videos. The proportion of neonates/infants with a quasi-normal score (≤10) will be compared between treatment groups.</td>
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</tbody>
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#### Inclusion Criteria
- Male or female infants, with PWS genetically confirmed
- Age ≤ 3 months
- Signed informed consent obtained from the parents
- Parents willing and able to comply with all study procedures

#### Exclusion Criteria
- Infants with exclusive nasogastric tube feeding
- Infants admitted to the emergency care unit for ongoing life-threatening comorbidities like severe respiratory, cardiovascular or neurological abnormalities
- Infants with hepatic insufficiency
- Infants with renal insufficiency
- Infants without medical insurance

#### Primary and Secondary objectives
- The primary objective is to assess the effect of OXT administration versus Placebo on sucking/swallowing after 1 month of 4IU intranasal OXT treatment administered every other day.
- The secondary objectives are to document:
  - i) the effect of OXT administration for 1 month on:
    - Sucking/swallowing
    - Food intake
    - Development (weight, growth and head circumference changes)
    - Behaviour
    - Circulating hormones involved in appetite behaviour, growth and metabolism
  - ii) the tolerance to repeated OXT administration for 1 month
  - iii) the best duration for daily administration of OXT between 1 and 2 months of treatment for
    - Sucking/swallowing troubles,
    - Social engagement
    - Mother-infant interactions,
    - Development as measured at month 3

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PedCRIN Funded OTBB3 Trial
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