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

Project : Objectives	Design & Phase	Countries	No. of Patients	Investigational Medical Product (IMP)	Follow-up End points	Start Date	End Date	Outcome measures
OTBB3 study Oxytocin treatment in babies with Prader-Willi syndrome: effects of intranasal administrations of oxytocin in infants aged from 0 to 3 months vs. placebo on sucking and swallowing (phase III clinical trial)	**Phase 3** Multicentre, prospective, randomized, placebo-controlled, double-blind clinical trial	**France** **Germany** **Belgium** **Italy** **Ntherlands**	52	Syntocinon: spray nasal (5ml; 40 UI/ml) Victoria Apotheke Pharmacy	5 months Duration of the inclusion period : 18 M Duration of each patient's participation: 5 M Total duration of the study: 3 years	01/11/2017	01/11/2020	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.

Inclusion Criteria	Exclusion Criteria	Primary and Secondary objectives
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	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	**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