

	STUDY PERIOD						
TIME	Screening Period	Delivery			End of postnatal stay		Follow-up evaluation
Time point		Baseline (≥3cm and < 10 cm dilation) Crossing the alert line	<sup>a</sup> IMP is given	30 min after IMP is given	Day of delivery	Day of discharge	1 month postpartum
<b>ENROLMENT:</b>							
Informed consent	X						
Inclusion/exclusion Evaluation	X						
Medical History	X						
Concomitant Medication	X	X					
<sup>b</sup> Physical Examination fetus (CTG)		X	X	X			
<sup>c</sup> Vital signs mother		X	X		X	X	
Cervical dilation		X					
<sup>d</sup> Pain measurement (VAS)			X	X			
<b>INTERVENTIONS:</b>							
Treatment administration			X				
<b>ASSESSMENTS:</b>							
Adverse event, mother			X	X	X	X	
Adverse event, newborn/fetus			X	X	X	X	
<sup>e</sup> Physical Examination newborn (pediatrician)						1 <sup>st</sup> day post partum	
Childbirth Experience Questionnaire							X