

# A clinical study to assess the efficacy of a probiotic supplement for women to reduce depression and anxiety symptoms after giving birth

<b>Submission date</b> 22/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/01/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The existence of communication between the brain and the gut, known as the Gut-Brain axis, has for long been recognized. Consequently, the importance of maintaining a healthy microbiota (microorganisms including bacteria that live in the digestive tract) community in the regulation of the gut-brain axis is of paramount importance. Probiotic supplementation has been suggested to maintain, through gut microbiota modulation, the physiological state of the mental and physical well-being. In this context the use of probiotics could be of support to new-mothers to reduce the possibility of the onset of anxiety or stress after childbirth.

### Who can participate?

Pregnant healthy women with no clinical history of depression.

### What does the study involve?

The study involves the administration of two different food supplements for 90 days after giving birth: one with probiotics + vitamins and the other with vitamins only.

### What are the possible benefits and risks of participating?

Risks associated with the intake of the product are considered from low to very low. Benefits associated with product use are amelioration of symptoms of depression and anxiety, of incidence of mastitis episodes, and of crying episodes of the child.

### Where is the study run from?

Humanitas San Pio X Hospital (Italy)

### When is the study starting and how long is it expected to run for?

September 2020 to July 2021

Who is funding the study?  
Roelmi HPC (Italy)

Who is the main contact?  
Dr Franco Vicariotto, ginecologia@vicariotto.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Franco Vicariotto

**Contact details**  
Humanitas San Pio X Hospital  
Via Francesco Nava, 31  
Milan  
Italy  
20159  
+39 3356698020  
ginecologia@vicariotto.com

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
K.E.HU.NN.NGN00.000.00.00\_2019/FV

## Study information

### Scientific Title

A randomized double blind controlled clinical study to assess the effect of treatment with a probiotic supplement targeted to women after pregnancy, to reduce postpartum symptoms of depression and anxiety

### Study objectives

The probiotic supplement is able to re-establish the microbial homeostasis in the gut and might positively influence the neural activity, resulting in the incidence reduction of depression or anxiety symptoms and post-natal stress.

### Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

Approved 13/11/2019, Independent Ethics Committee for Non-Pharmacological Clinical Investigations (Via XX Settembre 30/4, 16121 Genova - Italy; +39 105454842; ssinf@messaggipec.it), ref: 2019/12

## **Study design**

Multicenter randomized double-blind controlled clinical study

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Improvement of post-partum depression and mastitis in healthy new mothers and reduction of excessive crying in the newborns.

## **Interventions**

2 groups of 100 subjects were invited to orally take one capsule/day for 90 days, starting from delivery, as follows: one group (A) used the complete active treatment (Probiotics mix + multivitamin food supplement), one group (B) used the reference treatment (multivitamin food supplement). A restricted randomization list is generated by the site Study Coordinator using an appropriate statistic algorithm ("Wey's urn").

## **Intervention Type**

Supplement

## **Primary outcome(s)**

Depression and anxiety symptoms and post-natal stress measured using the Edinburgh Postnatal Depression Scale (EPDS) after 45 and 90 days

## **Key secondary outcome(s)**

1. Baby's crying, measured using Breastfeeding Self Efficacy Scale Short Form and Children Cry Questionnaires after 45 and 90 days.
2. Mastitis measured using Breastfeeding Quality Questionnaire after 45 and 90 days

## **Completion date**

26/07/2021

## **Eligibility**

### **Key inclusion criteria**

Healthy pregnant female subjects after their delivery

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

200

**Key exclusion criteria**

1. Subjects who do not meet the inclusion criteria
2. Subjects considered as not adequate to participate to the study by the investigator
3. Subjects with known or suspected sensitization to one or more test formulation ingredients
4. Adult protected by law (under control or hospitalized in public or private institutions for reasons other than research, or incarcerated)
5. Subjects not able to communicate or cooperate with the investigator for problems related to language, mental retardation or impaired brain function
6. Suffering from other psychiatric disorders such as schizophrenia, other psychotic disorders, bipolar disorder or substance use disorder
7. Serious physical illnesses or mental disorders due to a general medical condition which are judged by the investigator to render unsafe
8. A significant risk of infanticide according to the investigator assessment
9. Herbal remedies or psychotropic drugs that are intended for depression are taken within the last 2 weeks prior to baseline or during the study
10. Receiving counseling or psychological therapies at baseline or during the study
11. Participation in any clinical trial within the previous 3 months prior to baseline

**Date of first enrolment**

21/07/2020

**Date of final enrolment**

15/05/2021

**Locations****Countries of recruitment**

Italy

**Study participating centre**

**Humanitas San Pio X Hospital**

Via Francesco Nava, 31

Milan

Italy

20159

**Study participating centre**

**San Giovanni Addolorata Hospital**

Via dell'Amba Aradam, 9

Rome

Italy

00184

**Study participating centre**

**Careggi University Hospital**

Largo G. Alessandro Brambilla, 3

Flornce

Italy

50134

**Study participating centre**

**Sant'Anna e San Sebastiano Hospital**

Via Ferdinando Palasciano

Caserta

Italy

81100

**Study participating centre**

**University Hospital**

Viale Mario Bracci

Siena

Italy

53100

**Study participating centre**

**University Hospital**

Via Pozzuolo, 330

Udine

Italy

33100

**Study participating centre**

**University Hospital**

Piazza Luigi Miraglia, 2

Naples

Italy

80138

**Study participating centre**  
**A. Gemelli, University Hospital**  
Largo Agostino Gemelli, 8  
Rome  
Italy  
00168

**Study participating centre**  
**S. Andrea University Hospital**  
Via di Grottarossa, 1035/1039  
Rome  
Italy  
00189

**Study participating centre**  
**S. Pietro Fatebenefratelli Hospital**  
Via Cassia 600  
Rome  
Italy  
00189

## **Sponsor information**

**Organisation**  
Roelmi HPC

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
RoelmiHPC

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		09/08/2023	17/01/2024	Yes	No