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# Cranberry and enterocolitis in premature infants

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| **Submission date**<br>07/12/2010 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>06/04/2011 | **Overall study status**<br>Completed | |
| **Last Edited**<br>11/10/2011 | **Condition category**<br>Pregnancy and Childbirth | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
EC10-240

## Study information

**Scientific Title**

Randomised analysis, double blind and controlled with placebo of the utility of the extract of cranberry in the prevention of the enterocolitis of premature infants

## Study objectives
The blueberry extract has been used by mankind for over 200 years for indications related to the inhibition of bacterial adherence to epithelia, during this period, no adverse side effects have been reported. Through the prism of non-stick and anti-inflammatory activity of the polyphenols contained in the bilberry extract and its proven utility in the prophylaxis of other processes we propose the following hypothesis:
1. The blueberry extract (Vaccinium macrocarpon) is effective in the prevention of necrotising enterocolitis (NEC) in preterm infants, the equivalent of multimodal therapy given by G. Schmolze et. al., thus resulting in a reduced risk of NEC in more than 3.8%, without prescribing antibiotics
2. The microbiological changes of the intestinal flora induced premature newborn blueberry extract are in the spirit of fostering a proper bowel movements and digestive tolerance earlier than the placebo

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee San Cecilio Hospital (Spain) - not provided at time of registration

## Study design
Randomised double blind placebo controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Necrotising enterocolitis

## Interventions
1. Receive a dose of 0.5 ml of the prepared speech in the Pharmacy Department as unidosis in opaque vials. Opaque nasogastric administration every 12 hours.
2. (Placebo) - Receive a dose of 0.5 ml of the prepared speech in the Pharmacy Department as unidosis in opaque vials. Opaque nasogastric administration every 12 hours.

### Intervention Type
Drug

### Phase
Phase III

### Drug/device/biological/vaccine name(s)
Blueberry extract (Vaccinium macrocarpon)

### Primary outcome measure
1. Enterocolitis
2. The follow-up of each patient is 1 month
3. The total test duration is 3 years

### Secondary outcome measures
1. Poliphenols in urine
2. The follow-up of each patient is 1 month
3. The total test duration is 3 years

### Overall study start date
01/01/2011

### Completion date
31/12/2013

## Eligibility

### Key inclusion criteria
1. Preterm infants less than 1800 g birth weight, either sex
2. Infants with gestational age less than 32 weeks (depending FUR)

### Participant type(s)
Patient

### Age group
Neonate

### Sex
Both

### Target number of participants
238

### Key exclusion criteria
1. Newborns multiple malformations
2. Early neonatal sepsis
3. Does not provide consent to participate in the study

### Date of first enrolment

01/01/2011

**Date of final enrolment**
31/12/2013

# Locations

**Countries of recruitment**
Spain

**Study participating centre**
**Hospital Clínico San Cecilio**
Granada
Spain
18012

# Sponsor information

**Organisation**
Department of Health [Ministerio de Sanidad] (Spain)

**Sponsor details**
Unidad de Subvenciones para la Investigación
Dirección General de Farmacia y Productos Sanitarios
Ministerio de Sanidad y Política Social
C/ Paseo del Prado 18-20
Madrid
Spain
281071

**Sponsor type**
Government

**Website**
http://www.msps.es/en/home.htm

**ROR**
https://ror.org/00y6q9n79

# Funder(s)

**Funder type**
Government

**Funder Name**
Ministerio de Sanidad (Spain)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration