

Cranberry and enterocolitis in premature infants

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Hospital Clínico San Cecilio
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Granada
Spain
18012

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double blind placebo controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

ROR

<https://ror.org/00y6q9n79>

Funder(s)

Funder type

Government

Funder Name

Ministerio de Sanidad (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration