ISRCTN20343063 https://doi.org/10.1186/ISRCTN20343063

Cranberry and enterocolitis in premature infants

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jose Uberos

Contact details
Hospital Clínico San Cecilio
UCIPyN (9ª Planta)
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

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

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