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The usefulness of cranberry syrup versus antibiotic prophylaxis with trimethoprim in infantile recurrent urinary tract infection

Submission date	Recruitment status	[_] Prospectively registered
24/02/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/03/2017	Urological and Genital Diseases	

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
PI070274

Study information

Scientific Title
Randomised, double-blind analysis of the usefulness of cranberry syrup versus antibiotic prophylaxis with trimethoprim in infantile recurrent urinary tract infection

Acronym
CSRTUI

Study objectives
Given the state of uncertainty about the usefulness of antibiotic prophylaxis in children with vesicoureteral reflux we propose the following hypothesis:
1. How effective is the cranberry syrup in preventing recurrent urinary tract infections in children?
2. What organisms are mainly responsible for recurrent urinary tract infections in patients receiving prophylaxis with cranberry syrup?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee Clinical San Cecilio Hospital-dalucía (Spain), 04/01/2008

Study design
Randomised double-blind 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Recurrent urinary tract infection

Interventions
Experimental group receive an evening dose of 3 ml of cranberry syrup which ensures a fixed concentration of 36 mg of proanthocyanidins. The administration is done before dinner. If vomiting occurs within 30 minutes after administration, the dose is repeated in full.

Standard treatment group receive an standard treatment with trimethoprim at 0.2 ml/kg and masked with red cochineal. Management should be before dinner. If vomiting occur within 30 minutes after administration, the dose is repeated in full.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Recurrence of urinary tract infection

Secondary outcome measures
Secondary resistance to antibiotics

Overall study start date
01/01/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Children 0 to 5 years consulting for any of the points 2, 3 and 4 of this paragraph, on any visits to specialists of the Hospital Virgen de las Nieves, Clínico San Cecilio de Granada and Baza County Hospitals and Motril
2. More than a urinary tract infection confirmed by urine culture (> 100,000 colonies/ml) and sediment with more than 20 leukocytes per field, in a urine sample collected on the prowl or urine collection bag after urethral meatus asepsis with chlorhexidine
3. Existence of any degree vesicoureteral reflux confirmed by cystography or dilatation of the renal pelvis or urinary tract confirmed by ultrasound
4. Existence of any anatomical abnormality of the urinary tract that current protocols of action to justify continued antibiotic prophylaxis

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
5 Years

Sex
Both

Target number of participants
210

Key exclusion criteria
1. Coexistence of other infectious diseases
2. Coexistence of metabolic diseases
3. Renal failure
4. Hepatic impairment
5. Existence of allergy or intolerance to any component of cranberry or trimethoprim
6. I want to show the legal responsibility not to participate in the study

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clínico San cecilio
Granada
Spain
18012

Sponsor information

Organisation
Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain)

Sponsor details
Subdirección General Evaluación y Fomento de la Investigación.
Instituto de Salud Carlos III.
C/ Sinesio Delgado, 6
28029 Madrid
Madrid
Spain
28029

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Carlos III Institute of Health (Instituto de Salud Carlos III) (Spain)- Health Research Fund (Fondo de Investigaciones Sanitarias)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No