

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

<b>Submission date</b> 24/02/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/03/2017	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Jose Uberos

### Contact details

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Hospital Clínico San cecilio  
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Granada  
Spain  
18012

## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

Recurrence of urinary tract infection

**Key secondary outcome(s)**

Secondary resistance to antibiotics

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

0 years

**Upper age limit**

5 years

**Sex**

All

**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)

### 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

### 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?
<a href="#">Results article</a>	results	01/06/2015		Yes	No