

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

Submission date
24/02/2011

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
10/03/2011

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
10/03/2017

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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18012

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