

# Effects of an herbal mixture plus D-mannose on the prevention of recurrent uncomplicated cystitis

<b>Submission date</b> 13/01/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/01/2017	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Urinary Tract Infections (UTIs) are a common infection of the bladder, kidneys and their connecting tubes. They are more common in women than in men. Cystitis is a common type of UTI that involves the inflammation (swelling) of the bladder. Some of the symptoms of UTIs and cystitis are pain while urinating, needing to urinate more often, pain in the stomach, and blood in the urine. They usually get better by themselves, but when they occur regularly (recurrent UTIs) they are treated by antibiotics (medication that kills bacteria). Due to growing concerns about bacteria becoming resistant to antibiotics, alternative treatments, such as herbal remedies are now looked at as a way to prevent UTIs in order to reduce antibiotic usage. This study looks to see if herbal remedies can prevent recurrent UTIs and cystitis.

### Who can participate?

Women with recurrent UTIs and cystitis.

### What does the study involve?

Participants are randomly allocated to one of three groups. Participants receive capsules to take orally (by mouth) for 90 days. Those in the first group take capsules containing D-Mannose (a naturally occurring simple sugar) in the morning and then a capsule in the evening containing a mix of herbal ingredients. Those in the second group take a D-Mannose capsule in the morning and then a capsule in the evening containing a different mix of herbal ingredients to the first group. Those in the last group take only one capsule in the evening that contains a mix of D-Mannose and other herbal ingredients. After the 90 days, participants are followed up through clinical examinations and interviews to assess if they had any reports of UTIs or cystitis.

### What are the possible benefits and risks of participating?

Participants may benefit from a decrease in the amount of UTIs they have. There are no direct risks to those taking part in the study.

### Where is the study run from?

Castiglione Prestianni Hospital (Italy)

When is the study starting and how long is it expected to run for?  
March 2014 to December 2014

Who is funding the study?  
Pharmamol SRL (Italy)

Who is the main contact?  
Roberto Di Marco

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Roberto Di Marco

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
GynUro05

## Study information

**Scientific Title**  
Study on the effectiveness of an innovative combination of plant extracts (Berberine, Arbutin, Birch) that administered in conjunction with the D-mannose, for the prevention of recurrent urinary tract infections

**Study objectives**

The aim of this study is to assess the potential preventive effects of a nutraceutical (herbal mixture) formulation in patients affected by acute uncomplicated cystitis and with a history of recurrent cystitis.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Independent Ethical Committee for Non-Pharmacological Clinical Trials, 01/02/2014, ref: 2014/02

### **Study design**

Single centre randomised parallel trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Prevention

### **Participant information sheet**

No participant information sheet available

### **Health condition(s) or problem(s) studied**

Cystitis

### **Interventions**

All the patients meeting the inclusion criteria, who signed the informed consent form to participate in the clinical trial, are randomized to one of three arms ( A, B or C) to receive a three month prophylactic treatment.

Group A: Participants receive two capsules to ingest daily for 90 days consecutively. One capsule contains D-Mannose (78.8%) that is consumed in the morning and the other capsule contains Arbutin (61.9%), Birch (8.8%), and Berberin (5.4%), that is consumed in the evening.

Group B: Participants receive two capsules to ingest daily for 90 days consecutively. One capsule contains D-Mannose (78.8%) that is consumed in the morning and the other capsule contains Arbutin (62.8%), Birch (9%), Berberin (4.9%), and Forskolin (4.9%) that is consumed in the evening.

Group C: Participants receive capsules to ingest containing proanthocyanidins type A extracted from Cranberry (36 mg) and D-Mannose. This capsule is ingested once a day in the evening consecutively for 90 days.

After 90 days, participants are followed up until day 180 with a clinical evaluation if they have reported cases of cystitis. Participants who have not reported any cystitis are followed up by a phone interview.

**Intervention Type**

Supplement

**Primary outcome measure**

Symptomatic cystitis recurrence is measured through clinical evaluation and patient interviews at baseline, 90, 150/180 days.

**Secondary outcome measures**

Number of uropathogens is assessed using microbiological evaluation of urine sample, vaginal swab and a vaginal smear slide at baseline, 90 and 180 days.

**Overall study start date**

27/09/2012

**Completion date**

15/12/2014

**Eligibility****Key inclusion criteria**

1. Women with a history of recurrent cystitis, defined as:
  - 1.1. Participants must have two or more episodes of UTI in the last 6 months or 3-6 in the last 12 months
  - 1.2. Participants must have had an UTI that was documented by urine culture
2. Experienced episodes at least by one urinary symptom and/or positive urinary nitrate test or leukocyturia

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

70

**Key exclusion criteria**

1. Unable to provide informed consent
2. Pregnancy or lactation
3. Abnormalities of the upper urinary tract, including the presence of urinary stones
4. Patients with a permanent urinary catheter
5. Complete urinary incontinence
6. Patients with stage 5 chronic kidney disease (GFR <15 ml/min)

**Date of first enrolment**

31/03/2014

**Date of final enrolment**

13/06/2014

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre****Castiglione Prestianni Hospital**

C.so Umberto, 406

Bronte

Italy

95100

**Study participating centre****Biomedical and Biotechnological Sciences Department**

University of Catania

Piazza Università, 2

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**Study participating centre****Department of Medicine and Healthy Sciences**

Clinical Microbiology Laboratory

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## **Sponsor information**

**Organisation**

PharmaMol SRL

**Sponsor details**

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**Sponsor type**

Industry

**Website**

<http://www.pharmamol.com/index.htm>

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

Pharmamol SRL

## **Results and Publications**

**Publication and dissemination plan**

A manuscript summarizing the results of the study it is currently in preparation. The manuscript will be submitted to an high-impact peer-reviewed journal.

**Intention to publish date**

31/12/2017

**Individual participant data (IPD) sharing plan**

The current data sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Other