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

Submission date
13/01/2017

Recruitment status
No longer recruiting

Registration date
30/01/2017

Overall study status
Completed

Last Edited
31/01/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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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 much 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
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Study participating centre
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Sponsor information

Organisation
PharmaMol SRL

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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