ISRCTN55813586 https://doi.org/10.1186/ISRCTN55813586

Clinical dosage and effectiveness Study of ShanStar® Cranberry supplement for Prevention and Treatment against women's Urinary Tract Infections

Submission date	Recruitment status	[_] Prospectively registered
24/01/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2011	Urological and Genital Diseases	[_] Record updated in last year

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
3604-001

Study information

Scientific Title
Clinical dosage and effectiveness study of ShanStar® Cranberry supplement for prevention and treatment against women's urinary tract infections: a double blind, randomised, placebo-controlled clinical study

Acronym
SSCPTUTI

Study objectives
This study explores the effectiveness of ShanStar® Cranberry extract against recurrent urinary tract infections in women on the basis of symptoms, bacteriuria and pyuria in the urine and urine culture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study is to be conducted according to US and International standards of Good Clinical Practice and IRB guidelines, approved on 27/01/2011

Study design
Double blind randomised placebo-controlled clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Urinary tract infection

Interventions
ShanStar® Cranberry extract 150mg and 300mg per day. Participants in each group are given pills - 3 months supply. Participants are instructed to take one tablet twice a day by mouth for 3

months. At 1, 2 and final 3 months follow up, they will score the urinary tract infection (UTI) symptoms and provide urine for complete urine analysis and urine culture. Total duration of the treatment will be 3 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ShanStar® Cranberry extract

Primary outcome measure
At 1, 2, and 3 months, the participants will return to answer urinary tract symptoms questions and provide urine for complete urialysis and culture.
Primary outcome measures are:
1. Decrease in urinary tract infection symptoms score and decreased bacteriruia and pyuria and culture in urine study

Secondary outcome measures
No secondary outcome measures

Overall study start date
31/01/2011

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Age between the age of 18-50
2. Female gender
3. Healthy individual with 3 or more episodes of urinary tract infections per year
4. Able to complete the research study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex

Female

Target number of participants
60

Key exclusion criteria
1. Terminal diesease or dementia
2. Abstain from any cranberry, health food fruit extracts, anti-oxidants, vitamins, minerals and antibiotics for 2 weeks prior to participation in the study
3. Pregnancy
4. Urine catherisation within previous 2 weeks of study
5. Participants with history of diabetes, cardiovascular disease, symptoms of pyelonephritis and stones in the urinary tract
6. Sexually transmitted disease
7. Pyuria or bacteriuria on urinalysis or positive urine culture (will be treated and wait 2 weeks to be eligible)

Date of first enrolment
31/01/2011

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
United States of America

Study participating centre
16300 Sand Canyon Avenue
Irvine, California
United States of America
92618

Sponsor information

Organisation
ShanStar Biotech, Inc.

Sponsor details
1 Cliffstar Avenue
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Sponsor type
Industry

Website
http://shanstar.com/

Funder(s)

Funder type
Industry

Funder Name
ShanStar Biotech, Inc. (USA)

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