

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

Submission date 24/01/2011	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 18/03/2011	Overall study status Completed	☐ Protocol
Last Edited 18/03/2011	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number

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

Study type(s)

Other

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(s)

At 1, 2, and 3 months, the participants will return to answer urinary tract symptoms questions and provide urine for complete urinalysis and culture.

Primary outcome measures are:

1. Decrease in urinary tract infection symptoms score and decreased bacteriuria and pyuria and culture in urine study

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

Female

Key exclusion criteria

1. Terminal disease 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 catheterisation 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.

Funder(s)

Funder type

Industry

Funder Name

ShanStar Biotech, Inc. (USA)

Results and Publications

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

Not provided at time of registration