

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	<input type="checkbox"/> Prospectively registered
Registration date 18/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/03/2011	Condition category 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

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 bacterirua 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 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.

Sponsor details

1 Cliffstar Avenue

Dunkirk, NY

United States of America

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+1 716 363 3154
shanstarcustserv@cliffstar.com

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