Solace European Confirmatory Trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20657

Source
NTR

Brief title
SOLECT

Health condition

Stress Urinary Incontinence, SUI, Incontinence

Sponsors and support

Primary sponsor: AZM
academisch ziekenhuis Maastricht
Source(s) of monetary or material Support: Solace Therapeutics

Intervention

Outcome measures

Primary outcome

Improvement in quality of life as assessed by pad weight tests assessments and questionnaires.

Secondary outcome

1. Incidence of treatment-related adverse events;

2. Severity of treatment-related adverse events.

Study description

Background summary

N/A

Study objective

The Solace European Confirmatory (SOLECT) Trial is designed to determine whether the Solace Bladder Control System is safe and effective for the treatment of Stress Urinary Incontinence (SUI) in adult females.

Study design

1, 3, 6, 12, 18, 24, 30 and 36 months.

Intervention

Subject will undergo treatment with the Solace Bladder Control System or a sham procedure, with the results being compared at 3 months.

All patients undergoing sham treatment are treated at 3 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. Female 18 years of age or older with stress urinary incontinence (SUI);

2. Experienced SUI for at least 12 months and attempted and failed prior noninvasive treatment;

3. Willing to undergo cystoscopic procedures required and 36 month follow-up;

4. On stable medication for a minimum of 3 months;

5. Free of local genital skin infection;

6. Positive Pad Weight Test;

7. Free of impassable urethral strictures, trauma or necrosis.

Exclusion criteria

1. Pregnant or planning to become pregnant during the study period;

2. Non-ambulatory or bedridden or physically unable to complete test exercises;

3. Morbidly obese (defined as BMI ≥ 40 kg/m2);

4. Bladder infection (including bladder inflammation or edema) or UTI within 3 months;

5. History of recurrent urinary tract infections;

6. Prior surgical procedure for incontinence within the past 6 months;

7. Is taking medications for urinary incontinence other than anticholinergics;

8. History of kidney stones;

9. Has a prosthetic heart valve;

10. Unable to tolerate any form of antibiotic;

11. Taking anticoagulation therapy, other than aspirin;

12. Has urinary incontinence due to Intrinsic Sphincter Deficiency (ISD).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2012
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	30-01-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3640
NTR-old	NTR3828
Other	Solace Therapeutics : CD 1004
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A