Impact of peri-operative tEstosterone levels on oNcological and Functional Outcomes in RadiCal prostatEctomy (ENFORCE trial)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25840

Source
NTR

Brief title
ENFORCE

Health condition

Prostate cancer; testosterone deficiency

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Canisius Wilhelmina Ziekenhuis; Besins Healthcare

Intervention

Outcome measures

Primary outcome

The primary study endpoint is a clinically relevant (≥12 points) difference in the EPIC-26 domain for sexual functioning 12 months after RP in favor of TD men receiving TRT compared with TD men receiving placebo.

Secondary outcome

Secondary endpoints include: urinary incontinence, hormonal functioning and BCR-free survival.

Study description

Background summary

Radical prostatectomy (RP) is currently the most common treatment for localized prostate cancer (PCa) in the Netherlands. Two common side effects of this procedure are urinary incontinence (5-27%) and erectile dysfunction (57-89%), both having a significant negative impact on quality of life. It is known that with age the testosterone level in men declines; around 30% of men over 70 years of age meet the criteria of testosterone deficiency (TD). This does not necessarily lead to symptoms like decreased sexual desire, fatigue or erectile dysfunction. If men do have symptoms, the treatment of testosterone deficiency does improve energy levels and erectile function. Both RP and TD are well-established to have a significant negative impact on sexual performance and are likely to add up in TD patients following RP.
The aim of this study is to assess the efficacy of testosterone replacement therapy (TRT) on functional and oncological outcomes in testosterone deficient men following RP for PCa.

Study objective

Testosterone Therapy in (a)symptomatic, testosterone deficient men after Radical Prostatectomy improves functional and oncological outcome compared to testosterone deficient men who do not receive TRT.

Study design

3, 12 and 24 months follow-up after RP.

Intervention

Testosterone gel vs. placebo gel

Contacts

Public
Canisius Wilhelmina Ziekenhuis
Diederik Baas

024-3658832
Scientific
Canisius Wilhelmina Ziekenhuis
Diederik Baas

024-3658832

Eligibility criteria

Inclusion criteria

1. Unmeasurable PSA after Radical Prostatectomy (RP)
2. pT2-pT3a after RP
3. ISUP 1-3 regardless of surgical margins
4. ISUP 4-5 with negative surgical margins
5. At least one-sided nerve-sparing procedure
6. Baseline score sexual functioning domain of 40 points (EPIC-26)

Exclusion criteria

1. Metastatic disease (cN1/M1)
2. pT3b or pT4 after RP
3. Prior treatment for PCa
4. Prior TRT
5. Medical history of male breast- or liver carcinoma
6. Uncontrolled hypertension
7. General contra-indication for testosterone replacement therapy
8. Allergy for components in TRT-agent
9. Use of vitamin K-antagonists
10. BMI > 30

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	140
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-01-2021
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	NL9229
Other	CMO Arnhem Nijmegen : 2020-6874

Study results