

Testosterone replacement in young male cancer survivors

Submission date 04/02/2011	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 19/05/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/11/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-testosterone-replacement-in-young-men-who-have-had-cancer-treatment-trials>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

STH15216

Study information

Scientific Title

Testosterone Replacement in Young Male cancer Survivors: a prospective, multicentre, randomised, double-blinded, parallel-group, placebo-controlled phase III trial

Acronym

TRYMS

Study objectives

This trial aims to establish whether testosterone replacement therapy can improve body composition and quality of life in young hypogonadal male cancer survivors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Derby 1 Research Ethics Committee, 08/09/2011, ref: 11/EM/0164

Primary study design

Interventional

Study design

Prospective multicentre randomised double-blinded parallel-group placebo-controlled phase III superiority clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Testicular cancer, lymphoma or leukaemia and low testosterone level

Interventions

Patients are randomised to receive either the Tostran® 2% (testosterone) gel or placebo gel. There is a 26-week double-blinded treatment phase followed by a 13-week open-label active treatment phase for all participants.

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

1. Body composition, assessed after 26 weeks
2. Participant self-reported physical function scores, assessed after 26 weeks

Key secondary outcome(s)

1. BMI, blood insulin, glucose, lipid levels and bone density, assessed after 26 weeks
2. Participant self-reported quality of life, fatigue, self-esteem and sexual function scores, assessed after 26 weeks
3. Participant self-reported quality of life, fatigue, self-esteem and sexual function scores, assessed after 39 weeks

Completion date

31/01/2015

Eligibility

Key inclusion criteria

1. Able and willing to comply with all study procedures
2. Able to provide written informed consent
3. Male, aged between 25 and 50 years
4. Post-pubertal
5. Previous testicular cancer, lymphoma or leukaemia
6. At least 12 months from completion of curative treatment for testicular cancer, lymphoma or leukaemia
7. A serum testosterone level ≥ 7 nmol/l and ≤ 12 nmol/l
8. Taking any hormone replacement, on stable doses for the last 6 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

136

Key exclusion criteria

1. Body Mass Index (BMI) of more than 35 kg/m²
2. Currently receiving corticosteroid therapy or likely to receive corticosteroids during the trial
3. Previous testosterone treatment within 12 months of entering the trial
4. Previous allogeneic bone marrow transplant
5. A history of hormone-dependent cancer (e.g., prostate or breast cancer)
6. A history of primary liver tumour
7. Hypercalcaemia
8. Nephrotic syndrome
9. Diabetes
10. Other severe concurrent disease or mental disorders which would affect the collection of study measurements

Date of first enrolment

01/07/2011

Date of final enrolment

31/01/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9JT

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/018hjpz25>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (Reference A11891)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/11/2019	15/11/2019	Yes	No