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Testosterone replacement in young male cancer survivors

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

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-testosterone-replacement-in-young-men-who-have-had-cancer-treatment-tryms

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/07/2011

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

Age group
Adult

Sex
Male

Target number of participants
268

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
England

United Kingdom

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details
Research Department
1st Floor
11 Broomfield Road
Sheffield
England
United Kingdom
S10 2SE

Sponsor type
Hospital/treatment centre

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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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

Study outputs

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