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Lifestyle intervention in men with advanced prostate cancer receiving androgen suppression therapy

Submission date 23/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/09/2010	**Overall study status** Completed	
Last Edited 17/12/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Derek Rosario

Contact details
STH Teaching Hospitals,
The University of Sheffield,
School of Medicine and Biomedical Sciences,
Academic Urology Unit,
K Floor,
Royal Hallamshire Hospital,
Glossop Road,
Sheffield
United Kingdom
S11 7FE
-
d.j.rosario@sheffield.ac.uk

Additional identifiers

Protocol serial number
STH 14639

Study information

Scientific Title
Lifestyle intervention in men with advanced prostate cancer receiving androgen suppression therapy: a randomised control trial

Study objectives
1. Patients undergoing androgen suppression therapy (AST) randomised to a lifestyle intervention increase their total physical activity levels in comparison to a usual care control group over the period of the intervention and at six months of follow up.
2. Patients undergoing AST randomised to a pragmatic lifestyle intervention experience improvements in health-related outcomes in comparison to a usual care control group over the period of the intervention and at six months of follow up.
3. Patients undergoing AST randomised to a lifestyle intervention demonstrate improvements in biomarkers associated with disease progression in comparison to a usual care control group.

As of 03/05/2012, the following changes were made on the record.
Anticipated end date has been updated from 01/09/2009 to 01/01/2013.
Target number of participants has been updated from 50 to 100.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval and research governance approval for this study was granted by South Sheffield Research Ethics Committee and the Sheffield Teaching Hospitals research department on the 22nd of June 2007 (ref: 07/Q2305/3)

Primary study design
Interventional

Study design
Prospective randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Men with advanced prostate cancer receiving androgen suppression therapy

Interventions
A 12 week pragmatic, combined exercise and diet advice intervention (a "lifestyle" intervention) compared with usual clinical care controls.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 12/07/2013:
To be measured at baseline, 12 and 26 weeks:
1. Quality of life measured using the FACTP questionnaire
2. Diastolic blood pressure measured using an automated sphygmomanometer

Previous primary outcome measures:
1. Exercise behaviour measured using the Godin Leisure Score Index questionnaire at baseline, 12 weeks and 6 months of follow-up
2. Dietary intake measured using three day diet diaries over the intervention period

Key secondary outcome(s)
Current secondary outcome measures as of 12/07/2013:
To be measured at baseline, 12 and 26 weeks:
1. Fatigue measured using the FACT-F questionnaire
2. Aerobic exercise tolerance measured using the Bruce treadmill protocol
3. Body mass measured using balance beam scales
4. Systolic blood pressure measured using an automated sphygmomanometer
5. Exercise behaviour measured using the Godin leisure score index questionnaire and heart rate monitoring

To be measured at baseline and 12 weeks:
1. Dietary macro- and micro-nutrients measured using three-day diet diaries and Netwisp software
2. PSA measured using an immunoenzymatic assay
3. Serum lipid profile measured using an enzymatic colorimetric assay
4. Serum androgen profile measured using an electrochemiluminescence assay
5. Arterial health measured using flow-mediated dilatation

Previous secondary outcome measures:
1. Quality of life measured using the FACT-P questionnaire
2. Fatigue measured using the FACT-F questionnaire
3. Body Mass Index (BMI) and waist-to-hip ratio
4. Aerobic exercise tolerance measured using the Bruce treadmill protocol
5. Lower limb strength measured using isokinetic dynamometry
6. Functional capacity measured using the chair sit-to-stand test
Above outcomes measured at baseline, 12 weeks and at six months of follow-up.
7. Biomarkers associated with disease progression were assessed at baseline and after the intervention period.

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Histologically confirmed, non-localised prostate cancer (PCa)
2. Stable disease (stable prostate specific antigen [PSA])
3. Receiving Androgen suppression therapy (AST) for a minimum period of six months

4. A willingness to comply with the randomised allocation to intervention and willing to undertake the requirements of the allocated intervention. If allocated to the exercise intervention, willing to aim to achieve 80% compliance to the exercise intervention.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
Male

Key exclusion criteria
1. Participation in regular physical activity (defined as purposeful physical activity of a moderate intensity for 30 minutes three or more times per week in the previous six months)
2. Unstable angina, uncontrolled hypertension, recent myocardial infarction, pacemakers
3. Uncontrolled painful or unstable bone lesions
4. Less than two months post surgical treatment
5. Any physical, neurological or psychiatric impairment or disease such as dementia, multiple sclerosis, severe arthritis or other condition that would limit the ability to understand and complete the study exercises and complete the required questionnaires, recall and record of dietary information

Date of first enrolment
22/06/2007

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
STH Teaching Hospitals
Sheffield
United Kingdom
S11 7FE

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
University/education

Funder Name
Sheffield Hallam University (UK)

Results and Publications

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	feasibility study results	01/04/2011		Yes	No
Results article	results	14/11/2012		Yes	No
Results article	results	01/05/2014		Yes	No