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Multiple myeloma lifestyle study

Submission date 29/07/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/07/2015	**Overall study status** Completed	
Last Edited 22/05/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-lifestyle-after-treatment-for-myeloma

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16255

Study information

Scientific Title

Lifestyle study of patients with multiple myeloma

Study objectives
The aim of this study is to evaluate the practicality and feasibility of carrying out an exercise training programme in patients with myeloma (a cancer of the bone marrow), and to determine the benefits of such a programme. The programme will improve fatigue by clinically significant levels after 3 months of the exercise programme, when compared with usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Queen Square, 10/01/2014, ref: 13/LO/1105

Study design
Randomised; Interventional and Observational; Design type: Treatment, Cohort study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Haematological Oncology; Disease: Myeloma

Interventions
Patients are randomised to either a control group or to receive a physical activity intervention.

Patients in the control group receive usual care which includes their regular check-ups in the UCLH myeloma clinic and/or their local hospitals and receiving maintenance or consolidation treatment, if applicable.

Patients in the treatment arm are offered a physical activity programme, led by a physiotherapist, which requires them to attend a hospital gym once a week as well as carry out a home-based programme of exercises two days a week. After the 3 months patients attend the gym once a month and follow a home-based exercise programme three days a week for 3 additional months.

Patients in both control and intervention groups are assessed in terms of outcome measures at 3, 6 and 12 months follow up.

Follow Up Length: 12 month(s)

Intervention Type
Behavioural

Primary outcome measure
Fatigue; Timepoint(s): baseline, 3, 6 and 12 months

Secondary outcome measures
1. Anxiety and depression; Timepoint(s): baseline, 3, 6 and 12 months
2. Body mass and body composition; Timepoint(s): baseline, 3, 6 and 12 months
3. Diet; Timepoint(s): baseline, 3, 6 and 12 months
4. Exercise capacity and cardiorespiratory fitness; Timepoint(s): baseline, 3, 6 and 12 months
5. Haematology, biochemistry, bone health markers (basic ALP, osteocalcin); Timepoint(s): baseline, 3, 6 and 12 months
6. Muscle strength and endurance; Timepoint(s): baseline, 3, 6, 12 months
7. Physical activity; Timepoint(s): baseline, 3, 6 and 12 months
8. Resting blood pressure; Timepoint(s): baseline, 3, 6 and 12 months
9. Self-efficacy; Timepoint(s): baseline, 3, 6 and 12 months
10. Sleep quality; Timepoint(s): baseline, 3, 6 and 12 months
11. Well-being; Timepoint(s): baseline, 3, 6 and 12 months

Overall study start date
05/06/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Myeloma survivors, who are assigned to UCLH myeloma clinics
2. Stable disease for at least 6 weeks, off treatment or on maintenance or consolidation treatment
3. Ability to give informed consent
4. A good performance status (ECOG 02)
5. Clinically able to carry out an exercise training programme on a regular basis (assessed by initial screening)
6. Aged at least 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 138; UK Sample Size: 138; Description: Patients with Multiple Myeloma; 34 in control group and 104 in the intervention group (3:1 randomisation)

Total final enrolment
131

Key exclusion criteria
1. Spinal instability (as assessed on radiology in multidisciplinary team (MDT)) meetings
2. Those who have recently (within 4 weeks) had spinal or other surgery for pathological fractures
3. An abnormal resting ECG, where clinically indicated unexplained by further cardiological workup
4. At risk of pathological fracture (Mirel's score, see Appendix 1 of Protocol)
5. Already participating in an exercise programme as part of a research study
6. Unstable angina
7. Musculoskeletal disease limiting mobility
8. Cognitive impairment that impedes ability to complete questionnaires

Date of first enrolment
19/06/2014

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospital,
Haematology,
Cancer Division,
250 Euston Road,
London
United Kingdom
NW1 2PJ

Sponsor information

Organisation

University College London

Sponsor details
UCL Cancer Institute
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

Funder Name
Celgene Europe Ltd

Results and Publications

Publication and dissemination plan

The results of the trial will be disseminated in relevant scientific conferences and meetings. The results will also be written up as paper publications and submitted to scientific, peer-reviewed journals. This is planned for the end of 2016.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2020	22/05/2020	Yes	No
HRA research summary			28/06/2023	No	No