# Multiple myeloma lifestyle study

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

#### Contact name

Dr Maggie Heinrich

#### Contact details

University College London Gower Street London United Kingdom WC1E 6BT

# Additional identifiers

## Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

**United Kingdom** 

England

# Study participating centre University College London Hospital,

Haematology, Cancer Division, 250 Euston Road, London United Kingdom NW1 2PJ

# Sponsor information

#### Organisation

University College London

#### **ROR**

https://ror.org/02jx3x895

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

#### Cancer Research UK

## 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** 

#### **Funder Name**

Celgene Europe Ltd

# **Results and Publications**

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes