

# Tackling EARly Morbidity and Mortality in myeloma (TEAMM)

<b>Submission date</b> 10/08/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/11/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-antibiotic-prevent-infections-people-having-treatment-myeloma-teamm>

## Contact information

### Type(s)

Scientific

### Contact name

Ms Kerry Raynes

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2011-000366-35

### Protocol serial number

10626; HTA 08/116/69

## Study information

Scientific Title

Tackling early morbidity and mortality in myeloma: assessing the benefit of antibiotic prophylaxis and its effect on healthcare associated infections

## Acronym

TEAMM

## Study objectives

TEAMM is a randomized, double-blind, placebo-controlled multi-centre phase III clinical trial assessing the benefit of antibiotic prophylaxis and its effect on health care associated infections.

The trial hypotheses are that levofloxacin used once daily as anti-bacterial prophylaxis in newly diagnosed symptomatic myeloma will:

1. Reduce the rate of febrile episodes, hospitalisation, and death
2. Increase response to anti-myeloma therapy
3. Improve quality of life and overall survival

The trial will also test if levofloxacin affects the carriage of and invasive infection by three important groups of bacteria; *C. difficile*, *S. aureus* (including methicillin-resistant *Staphylococcus aureus* [MRSA]) and Extended-Spectrum Beta-Lactamases (ESBL) coliforms.

1. Is the carriage of these organisms increased in patients receiving levofloxacin compared to those receiving placebo?
2. Is the carriage of these organisms associated with later invasive infections?
3. Does levofloxacin increase the rate of invasive infections by these three groups of organisms?

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/0811669>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0020/52076/PRO-08-116-69.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0020/52076/PRO-08-116-69.pdf)

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

First MREC, 27/07/2011, ref: 11/WM/0220

## Study design

Randomised interventional prevention trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Haematological Oncology; Disease: Myeloma

## Interventions

Antibiotic prophylaxis: 500mg of Levofloxacin or Placebo to match will be taken daily for 12 weeks during anti-myeloma chemotherapy

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Levofloxacin

## **Primary outcome(s)**

Number of febrile episodes from randomisation up to 12 weeks

## **Key secondary outcome(s)**

1. Carriage and invasive infections with *S. aureus*, *C. difficile* and ESBL coliforms between 12 and 16 weeks to assess for delayed effects from the intervention that is stopped at 12 weeks
2. Carriage and invasive infections with *S. aureus*, *C. difficile* and ESBL coliforms from randomisation up to 12 weeks
3. Days on antibiotic therapy for treatment of infection from randomisation up to 12 weeks
4. Health economics - captured daily for the first 16 weeks post randomisation
5. Incidence of microbiologically proven infections, the pathogens and their susceptibility to antibiotics from randomisation up to 12 weeks
6. Number of days in hospital on antibiotics from randomisation up to 12 weeks
7. Number of clinically documented total infections, episodes of severe sepsis (CTCAE grade 3 or 4) from randomisation up to 12 weeks
8. Number of days in hospital from randomisation up to 12 weeks
9. Number of deaths and infection related deaths from randomisation up to 12 weeks
10. Overall survival at 1 year post randomisation
11. Patient characteristics, steroid usage and indices of immunocompetence from randomisation up to 12 weeks
12. Quality of life measured 4 weekly up to 16 weeks from randomisation
13. Response to anti-myeloma therapy at 16 weeks. Because of the half life of paraproteins measurement of myeloma response cannot be under 16 weeks
14. Response to anti-myeloma therapy and its relationship to infection from randomisation up to 12 weeks

## **Completion date**

31/05/2017

## **Eligibility**

### **Key inclusion criteria**

1. Aged minimum of 21 years and able to give informed consent
2. Patient with newly diagnosed symptomatic myeloma based on internationally agreed criteria, within 7 days of starting a programme of anti-myeloma therapy (or within 14 days of starting anti-myeloma therapy if already on a broad spectrum antibacterial agent)
3. Provision of written informed consent
4. Male or female participants

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

977

**Key exclusion criteria**

1. Patients with contraindication to Levofloxacin:
  - 1.1. Known to have sensitivity/allergy to Levofloxacin or other quinolones
  - 1.2. Patients with a history of tendon disorders related to fluoroquinolone administration
  - 1.3. Patients receiving other prophylactic antibiotic treatment (excluding pneumocystis prophylaxis if regarded as essential)
  - 1.4. Patients receiving amiodarone or arsenic trioxide
  - 1.5. Patients on active antiepileptic treatment
2. Women of childbearing age who are not willing to use appropriate methods of contraception to prevent pregnancy or women that are breastfeeding
3. Patient thought to have mandatory requirement for prophylactic antibiotics
4. Patient who is not going to receive anti myeloma therapy

**Date of first enrolment**

13/04/2012

**Date of final enrolment**

30/04/2016

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Warwick Medical School**

Gibbet Hill Road

Coventry

United Kingdom

CV4 7AL

**Sponsor information**

## Organisation

University of Birmingham (UK)

## ROR

<https://ror.org/03angcq70>

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are available on reasonable request from [teamm@warwick.ac.uk](mailto:teamm@warwick.ac.uk), subject to approval from the trial management group and a data transfer agreement and contract.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2019	04/11/2019	Yes	No
<a href="#">Results article</a>	results	01/11/2019	08/11/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
	Participant information sheet				

<a href="#">Participant information sheet</a>		11/11/2025	11/11/2025	No	Yes
<a href="#">Plain English results</a>				No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes