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Tackling EArly Morbidity and Mortality in myeloma (TEAMM)

Submission date 10/08/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 08/11/2019	**Condition category** Cancer	[_] 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

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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

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 27/07/2011, ref: 11/WM/0220

Primary study design
Interventional

Study design
Randomised interventional prevention trial

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 affects 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 randomisatio
13. Resonse 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
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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, 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?
Results article	results	01/12/2019	04/11/2019	Yes	No
Results article	results	01/11/2019	08/11/2019	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results				No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes