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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/08/2011	**Overall study status** Completed	
Last Edited 08/11/2019	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-trial-looking-antibiotic-prevent-infections-people-having-treatment-myeloma-teamm

Study website
http://www.warwick.ac.uk/go/teamm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2011-000366-35

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

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 measure
Number of febrile episodes from randomisation up to 12 weeks

Secondary outcome measures
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

Overall study start date
01/09/2011

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: up to 1000; UK Sample Size: up to 1000

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
England

United Kingdom

Study participating centre
Warwick Medical School
Gibbet Hill Road
Coventry
United Kingdom
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Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Department of Immunity and Infection
Edgbaston
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Sponsor type
University/education

Website
http://www.birmingham.ac.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, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date.
14/03/2018: Results were presented at the American Society for Hematology annual meeting 2017 https://ash.confex.com/ash/2017/webprogram/Paper106598.html

Intention to publish date
31/05/2018

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?
Plain English results				No	Yes
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