

Zoledronic acid in the management of malignant pleural mesothelioma

Submission date 27/07/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/08/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/04/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-zoledronic-acid-and-chemotherapy-for-people-with-mesothelioma-zol-a>

Contact information

Type(s)

Scientific

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Additional identifiers**EudraCT/CTIS number**

2015-004433-26

IRAS number**ClinicalTrials.gov number****Secondary identifying numbers**

30497

Study information**Scientific Title**

A double-blind randomised controlled trial (RCT) to assess the feasibility of giving Zoledronic acid alongside chemotherapy in patients with mesothelioma to design a larger trial to assess the efficacy of Zoledronic acid alongside first line chemotherapy

Acronym

ZOL-A

Study objectives

The aim of this study is to investigate the feasibility of running a trial to establish the role of zoledronic acid (ZA) in patients who have mesothelioma and are undergoing or eligible for chemotherapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East of England - Cambridge East Research Ethics Committee, 10/05/2016, ref: 16/EE/0105

Study design

Randomised; Interventional; Design type: Treatment, Drug, Imaging

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Specialty: Respiratory disorders, Primary sub-specialty: Respiratory disorders; UKCRC code/

Disease: Cancer/ Malignant neoplasms of respiratory and intrathoracic organs

Interventions

Patients will be randomised using varying block sizes on a 1:1 to one of two groups using web based software developed by Sealed Envelope. Randomisation will be stratified according to histological subtype. Participants will be allocated to either the IMP (Zoledronic acid) or placebo arms.

Participants in both arms of the trial will receive the infusion on the day of their chemotherapy, just prior to start of their chemotherapy treatment. They will have the same number of cycles of the IMP/placebo, as chemotherapy. Those who stop chemotherapy treatment early will stop IMP /placebo treatment too.

A renally adjusted dose of Zoledronic acid or placebo will be administered in 100ml of 0.9% saline via an intravenous cannula over 15 minutes alongside each session of chemotherapy (every 3 weeks, up to a maximum of 6 cycles). Randomised patients will be stratified by histological subtype and allocated to either Zoledronic acid or placebo. A third non-randomised arm of the trial is available to patients who decline chemotherapy but would like an opportunity to have Zoledronic acid on its own (every 3 weeks, up to a maximum of 6 cycles).

Follow up will occur after each cycle, at end of treatment and at 6 months, and involves information gathering on any AEs or SAEs relating to the IMP. Participants will also have blood tests at their follow-up appointments to ensure they are able to continue with the next cycle of chemotherapy treatment/IMP or placebo.

Intervention Type

Other

Primary outcome measure

1. Recruitment rate is recorded as the number of eligible participant who consent to participate in the study by 6 months
2. Acceptability of recruitment procedures, consent and randomisation, and data collection methods are measured through patient interviews conducted at 6 months
3. Tolerance of the IMP treatment will be measured by the proportion of patients who complete the full 6 cycles of treatment
4. Intolerance will be recorded for those who are unable to continue to with the IMP due to electrolyte disturbances or AEs relating to the IMP and come off treatment before completing 6 cycles

5. Efficacy data will be measured using CT scans, PET-CT scans and Mesothelin bloods tests. On CT a > 15% reduction in the modified RECIST score would be classed as a disease response. CT will be performed at post 3 cycles and at 6 months from enrolment

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/04/2016

Completion date

24/07/2018

Eligibility

Key inclusion criteria

1. Histologically confirmed diagnosis of MPM
2. WHO performance status 0-1
3. Eligible for first line chemotherapy treatment Measurable disease on CT as per modified RECIST criteria (tumour thickness > 5mm)
4. Ability to give informed consent
5. Aged 18 years and over

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 70; UK Sample Size: 70

Total final enrolment

22

Key exclusion criteria

1. Not fit for chemotherapy due to performance status or other comorbidities Previous chemotherapy for MPM
2. IV bisphosphonates in the 3 months preceding randomisation
3. Significant renal disease (eGFR < 30ml/min in the last 4 weeks)
4. Hypocalcaemia (current hypocalcaemia on treatment, evidence of hypocalcaemia on most recent blood tests - should be within last 6 weeks)
5. Pregnancy or lactation Age
6. Age < 18 years

7. Known allergy to bisphosphonates or excipients of its preparation
8. Severe untreated dental caries
9. Concomitant participation in another drug trial for mesothelioma

Date of first enrolment

01/09/2016

Date of final enrolment

31/08/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Clinical Research Centre - Respiratory**

Southmead Hospital

North Bristol NHS Trust

Bristol

United Kingdom

BS10 5NB

Sponsor information

Organisation

North Bristol NHS Trust

Sponsor details

Research & Innovation

Learning & Research Building

Southmead Hospital

Westbury-on-Trym

Bristol

England

United Kingdom

BS10 5NB

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/036x6gt55>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Results will be presented at an international mesothelioma research meeting such as International Mesothelioma interest Group (iMiG) and published in a peer reviewed scientific journal.

Intention to publish date

31/07/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/08/2018		Yes	No
Basic results		22/07/2019	22/07/2019	No	No
Basic results			21/04/2020	No	No
HRA research summary			28/06/2023	No	No